

University of Dundee

DOCTOR OF PHILOSOPHY

The Feasibility of Clinical Research in Undergraduate Dental Outreach

Richardson, Kerry Norval

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The Feasibility of Clinical Research
in
Undergraduate Dental Outreach

Kerry Norval Richardson

Doctor of Philosophy

University of Dundee

2018

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Abbreviations

Below is a list of abbreviations utilised throughout:

CPD	-	Continuing Professional Development
CRF	-	Case Report Form
DOOHS	-	Dental Outreach Oral Hygiene Study
FTA	-	Failure to Attend (of a dental patient)
GCP	-	Good Clinical Practice
GDC	-	General Dental Council
GDP	-	General Dental Practitioner
GDS	-	General Dental Services
IRAS	-	Integrated Research Application System
KR	-	Kerry Richardson
NES	-	NHS Education for Scotland
NICE	-	The National Institute for Health and Care Excellence
NRAS CC	-	National Register of Archives for Scotland
OHI/OHA	-	Oral hygiene advice/oral hygiene instruction
OHSAS	-	Occupational Health and Safety Advisory Service
PI	-	Principal Investigator
RGF	-	Research Governance Framework
SDPBRN	-	Scottish Dental Practice Board Research Network
SDS	-	Salaried Dental Service
SIGN	-	Scottish Intercollegiate Guidelines Network
SPSS	-	Statistical Package for the Social Sciences

TAHSC	-	Tayside Academic Health Sciences Centre
TIPPS	-	Talk, Instruct, Practice, Plan, Support
VT	-	Vocational Trainee

Preface

The last ten years have seen dental undergraduates increasing the amount of time they spend in outreach clinics. Although increasing numbers of dental procedures are being carried out in dental outreach, this cohort of dental patients have never, until now, been involved in clinical research. Nor have dental undergraduates had the opportunity to carry out prospective clinical research studies as part of their training.

This investigation into the feasibility of carrying out clinical research in dental outreach, afforded both outreach patients and dental undergraduates the opportunity to gain firsthand experience of clinical research.

On embarking on this work, from my background as a Senior Dental Officer for outreach, I had expected the outreach patients (who already spent a long time in the dental chair receiving treatment), not to wish to spend further time on the clinic. I further expected dental undergraduates, who often ask about the evidence base for dentistry, to be excited about the opportunity to pioneer dental research in outreach. This work found surprises in both areas.

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Author's Declaration

I declare that this Thesis is my own composition and has not been previously submitted or accepted for a higher degree. Unless otherwise stated, all references cited have been consulted.

.....

Kerry Norval Richardson

Dundee

October 2017

.....

Dr A Hall

Supervisor

Dundee

October 2017

.....

Prof J Clarkson

Supervisor

Dundee

October 2017

Abstract

Aim:

To test the feasibility of undergraduate dental outreach clinics as an environment in which to support the conduction of clinical research studies.

Methods:

In order to test the ability to carry out clinical research in dental outreach clinics, a simple trial was set up to be conducted in outreach clinics. The Dental Outreach Oral Hygiene Study (DOOHS) was a prospective randomised controlled cluster trial investigating the effectiveness of oral hygiene instruction. This trial was based on a previously used clinical study but was conducted in dental outreach clinics. It involved the six dental outreach clinics attended by University of Dundee dental students at the time and two year groups of final year dental students. For the purposes of the study, dental students were trained as clinical researchers. Students underwent Good Clinical Practice and study protocol training. The intervention students were additionally trained to deliver the intervention oral hygiene instruction which was enhanced with a psychological framework of Tell-Show-Do-Plan. All dental students under the supervision of outreach clinicians were considered collaborators in the clinical research.

The post study views of supervisors, patients and final year dental students involved with DOOHS were collected by questionnaire and focus groups. These together with the results of the study were used to assess the feasibility of the environment for clinical research.

DOOHS Results:

Two year groups of final year dental students underwent training and subsequently collaborated with the clinical research study 'DOOHS'. All dental outreach clinics associated with the University of Dundee at that time were involved.

DOOHS recruited 165 participants across 6 outreach clinics. Sixty-four percent of participants return for clinical (plaque and bleeding) measures at three months and 75% of questionnaire returns at three months. At six months this dropped to 55% of the original number of participants returning for clinical measures and 63% of questionnaire returns.

Both the intervention and control groups saw a reduction in plaque scores at three months. This was statistically significant for the intervention group (Related samples Friedman's Two-Way Analysis of Variance by Ranks, Significance 0.002).

Overall Results:

The clinical study approvals were granted without problem. NHS R&D approval took a long time and this held up the start date of DOOHS.

By their final year, dental students are not particularly interested in carrying out clinical research studies investigating something as simple as oral hygiene instruction. Clinical research needs to be 'sold' well to dental students and properly integrated into the undergraduate curriculum if students are to consider it part of 'normal' dentistry. Training dental students for collaboration in clinical research studies needs to be carried out by clinicians who are used to teaching students, not researchers if the students are to maintain interest in the topic. Dental outreach clinics require additional support for clinical research studies, especially the paperwork which was considered arduous. Dental nurses prove to be essential to organisation of the students during the research period and to the tracking of participants during the study and therefore to the clinical research process.

Conclusions:

It is feasible to conduct clinical research studies in undergraduate dental outreach clinics however close attention needs to be paid to the timing within the curriculum, the design of the study and training of dental students. Clinics require additional administrative support. Dental nurses are essential to clinical research in dental outreach.

Chapter 1: Introduction

Evidence based clinical practice in dentistry requires access to evidence which, for much of the time, is missing or inadequate. Clinical trials are one way of collecting evidence about the efficiency of treatment. Such trials may often be seen as the work of multi-national pharmaceutical companies but that should not be the case. Clinical trials require careful planning, the permission of the ethics committee, the permission of other regulatory bodies, consent of those taking part and careful evaluation and interpretation of the results. Clinical research within an Outreach setting during the final year of the BDS course could offer an unique educational opportunity for the dental students involved as well as the possibility of collecting meaningful clinical data. This chapter discusses the challenges to the provision of evidence-based dental care (Section 1.1) and the requirement for further prospective clinical studies within primary care dentistry (Section 1.2.1, 1.2.2) as well as the challenges of clinical research in this area (Section 1.2.3). Alternative primary dental care environments which could be utilised to deliver clinical research are discussed (Section 1.2.4).

Dental outreach is addressed in Section 1.3. This includes the background to outreach (1.3.1) and the function of the current dental outreach model.

Dental outreach at the University of Dundee follows (Section 1.4). This includes the background and journey of dental outreach at Dundee (Section 1.4.1), the Dental Action Plan and the impact of this on dental outreach at Dundee (Section 1.4.2) and the dental care delivered in outreach clinics by University of Dundee dental students (Section 1.4.3). Current dental outreach facilities at the University of Dundee are outlined (Section 1.4.4) and consideration given to the suitability of dental outreach as a primary care research environment (Section 1.4.5). The potential feasibility of these clinics to support clinical research is finally discussed (Section 1.5).

1.1 Evidence Based Dentistry

There is an increased focus in clinical dentistry on the delivery of evidence-based care (McGlone et al. 2001; Watt et al. 2009). Patients now have access to a wide range of health information online, and healthcare providers are increasingly required to justify the treatments they provide and implement guidelines practicing clinical governance. Furthermore, the current economic climate and reductions in healthcare funding mean that evidence-based clinical care has increased emphasis.

Providing evidence based care in dentistry can be challenging (Iqbal & Glenny 2002). Busy general dental practitioners have a wide choice of journals to read which contain studies of varying design, bias, statistical analysis and qualities to be interpreted. Many of the clinical procedures under investigation are operator sensitive; carried out on select populations and traditionally such studies been carried out in academic institutions or by international companies. Results of such studies may not be transferrable to primary care dentistry to be delivered by general practitioners with limited time and resources.

There are many groups addressing this challenge of providing information for dentists regarding evidence-based dental practice. Journals such as Dental Update and the Journal of Evidence Based Dentistry provide easy to read articles summarising the key points of recent and relevant dental research. There are guidelines available from groups such as National Institute of Health and Care Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN). However, there are relatively small numbers of dental guidelines published by these groups: three NICE and three SIGN dental guidelines have been published. The Scottish Dental Clinical Effectiveness Programme (SDCEP) produces evidence-based guidelines specifically for dentistry and currently have ten publications relevant to General Dental Practitioners (GDPs).

In addition to the published guidelines, GDPs could be expected to interpret and incorporate into their practice a number of systematic reviews which have been carried out in dentistry. Systematic reviews allow GDPs to easily access the results of several studies in a field, which have already been assessed for quality of study

and bias and thereafter the evidence is synthesised to give an overall recommendation in the area. The most rigorous of these systematic reviews are carried out by the Cochrane Collaboration.

1.2. Requirement for Further Prospective Clinical Studies within Primary Care Dentistry

1.2.1 Cochrane Reviews in Oral Health Topics

The Cochrane Collaboration is a worldwide organisation promoting evidence based healthcare. They coordinate researchers and healthcare providers who conduct independent, systematic reviews of evidence across a wide variety of healthcare areas.

Oral health topics have been addressed in 157 out of 5914 published Cochrane systematic reviews. These reviews have assessed thousands of studies for bias and rigor across the topics. Due to very strict inclusion criteria however, many reviews find that few studies are suitable for inclusion in their synthesis. The common finding from Cochrane reviews in oral health is the requirement for further high quality studies within each subject area. There is a clear need for further well designed dental research, especially within the area of primary care dentistry.

1.2.2 Challenges of Primary Care Dental Research

Within Scotland, 4.4 million patients were registered with a GDP during 2013 (Information Services Division Scotland 2013). This equated to approximately 83.4% of the population of Scotland. These GDPs carry out the majority of dental care within Scotland.

It is recognised that clinical dental research has, in the main, been carried out in academic environments, such as university hospitals, and involves a different group of patients which make up a small proportion of the population receiving dental care.

It is additionally recognised that these results may not translate into primary dental care (Mant 1997). It has been suggested that in order to ensure the transferability of research results to general dental practice, further clinical studies should be carried out in the primary dental care environment (Clarkson 2004; Jones et al. 2004; Wilson 2004; Hopper et al. 2008). The large number of patients receiving dental care in general practice also makes primary care an obvious choice for collecting research data. There are documented challenges to recruiting dentists to clinical studies in general practice (Bahrami et al. 2004; Blinkhorn et al. 2000) and barriers to the delivery of clinical studies in primary care dentistry (Clarkson 2004).

In terms of barriers, Hopper (Hopper et al. 2011), identified that GDPs cited the following barriers to carrying out clinical research in primary dental care:

- loss of clinical freedom and control
- disruption to practice
- concerns for their patients' welfare
- additional workload
- insufficient time
- financial loss

Clarkson (Clarkson et al. 2004) further discussed barriers to GDPs carrying out clinical research in practice and found that GDPs reported the following research barriers:

- lack of interest
- lack of involvement
- lack of time
- lack of remuneration

The recruitment of GDPs to undertake clinical research studies has therefore been challenging. Bahrami (Bahrami et al. 2004) approached 565 GDPs to participate in

their research into Third Molar Guidelines and found only 51 actually willing to take part in their research.

1.2.3 Addressing the Challenges to Primary Care Dental Research

Within Scotland, the Scottish Dental Practice Based Research Network (SDPBRN) has led the way in encouraging evidence-based clinical practice through the development of easy-to-access clinical guidelines on a range of dental topics. SDPBRN have been successful in establishing several clinical studies which involve dental practices within Scotland and also nationally. However, even with this support for clinical research studies within primary care dentistry, only a minority of GDPs are engaged with clinical research studies. SDPBRN's efforts to encourage collaboration of GDPs to take part in clinical research has facilitated the engagement of new graduates with clinical studies during their Vocational Training (VT) year during which they are paid a salary rather than a fee-per-item of service remuneration scheme. The payment of a salary could address Clarkson (Clarkson 2004) and Hopper's (Hopper et al. 2008) findings of financial loss and lack of remuneration being a reason to decline involvement in delivering clinical studies. In addition, the VTs attend tutorials and study days, which makes them well placed to receive group training for clinical research, allowing ease of organisation and involving several dental practices in a single session.

Practice-based research networks offer support and advice to GDPs wishing to get involved in clinical research and, on occasion, recruit practitioners keen to be involved (Kay et al. 2003). However they often still struggle to recruit enough dentists. Blinkhorn (Blinkhorn et al. 2000) approached 872 dentists to join a practice-based research network. Of those approached, Blinkhorn found that only 98 GDPs signed up to the network and of those, they received only one request for assistance with a research project. Burke and Crisp set up the Product Research and Evaluation by Practitioners (PREP) panel in 1993. This PREP panel have a team of 25 GDPs who carry out practice-based clinical trials on new products, succeeding in publication of practice-based research in peer reviewed journals (Crisp et al. 2008; Burke et al. 2007; Burke et al. 2006; Burke et al. 2005; Stewardson et al. 2004;

Burke et al. 2003; Burke et al. 2001 Burke & Crisp 2001; Burke et al. 2000; Crisp & Burke 2000; Crisp & Burke 1998)

Despite the fact that GDPs have access to a wide-ranging, accessible and relevant group of patients and despite support being available for them to get involved in research, there are still a number of barriers to overcome. Alternative primary dental care environments could perhaps be considered for clinical research studies.

1.2.4 Alternative Primary Care Environments

The Salaried Dental Service (SDS) - previously called the Community Dental Service (CDS), provides an alternative dental service for those patients who are unable to register or receive treatment from a GDP. The primary function of the SDS is to act as a 'safety net' for patients who are unable to register with GDPs, ensuring unregistered patients can gain access to NHS dental services. In addition to the provision of dental treatment, the SDS is responsible for the delivery of population targeted preventive strategies such as Childsmile™ under the directive of the Scottish Government. The SDS also conducts the National Dental Inspection Programme (NDIP), which involves screening school children for dental caries. Although this is not an interventional clinical research study, the paperwork and calibration involved in NDIP has aspects similar to many clinical research studies. This primary dental care environment has previously delivered clinical research studies, both in practice and in schools.

Within the last ten years, the SDS has undergone substantial change. Housed under the umbrella of the SDS are the new dental outreach clinics. Dental outreach clinics provide primary care dentistry across Scotland. However such care is delivered by final year dental students under the supervision of the Salaried Dental Officers.

1.3 Dental Outreach

1.3.1 Dental Outreach – Concept and Purpose

Delivering dental education in settings out with the dental hospital environment is not a new concept. In 1977 Holloway and Dixon (Holloway & Dixon 1977) discussed the advantages to students of attending general practice clinics out with the dental school. They discussed the increase in undergraduates' awareness of social circumstances of dental patients with the consequent impact this can have on treatment planning, the improvement in undergraduates' understanding of primary care dentistry, the needs of the community and the increase in breadth of clinical experience .

Many of the reasons for dental undergraduates attending general practice clinics out-with the hospital environment thirty-seven years ago, remain the same for students attending outreach clinics today. Recent research into dental outreach education affirms the initial findings of Holloway and Dixon (Holloway & Dixon 1977), while highlighting the benefits of outreach to the undergraduate dental curriculum. (Eaton et al. 2006; Smith et al. 2006; Elkind, et al. 2007; Hunter et al. 2007; Craddock 2008; Ireland 2008; Maguire et al. 2009; Lynch et al. 2010; Eriksen et al. 2011; Smith et al. 2011). In addition to supporting the findings of Holloway and Dixon (Holloway & Dixon 1977), recent outreach research has identified further benefits.

One of the primary roles of dental outreach clinics is to provide dental care for patients who have been without a dentist for several years. Dental students therefore gain valuable experience in treating primary dental disease in a patient population with higher need. These high disease levels have been demonstrated to have improved undergraduate confidence in treatment planning while consolidating their clinical skills (Smith et al. 2006). Managing higher levels of primary disease provides a new experience for undergraduates who may have spent much of their time in the dental hospital replacing existing restorations and prosthesis. These higher levels of disease (Elkind et al. 2005; Craddock 2008) also focus the importance of prevention in treatment planning (Craddock 2008).

The different supervisors who work on outreach clinics add to the rich diversity of outreach and further broadens the student experience. The focus of dental outreach education is not on the teaching of new skills but very much on the consolidation of skills already learnt within the dental school (Smith et al. 2011). Students can improve their skills and learn new approaches. For example, they may experience a range of dental materials. Team-working and the improvement of communication skills is another additional benefit (Elkind et al. 2005; Smith et al. 2011).

Students attending outreach strengthens links between educational institutes and the NHS and is considered to positively impact on local communities (Smith et al. 2011). Experiencing the challenges of ‘real-life’ dentistry allows students to learn to make the most of their clinical time and how to manage the challenges of general dental practice such as treatment planning, emergency patients, running late, organising appointments and not having a laboratory on site (Craddock 2008).

The primary aim and benefit remains to develop and broaden dental students’ range of skills and experience in preparation for ‘real world’ primary care dentistry. This consolidation of skills and increase in students’ confidence prepares undergraduates for the move to Vocational Training and, thereafter independent practice. Dental outreach education is very much an essential part of the undergraduate curriculum (GDC 2013).

All dental schools within the UK include dental outreach teaching within their undergraduate curriculum. The timing of dental outreach varies between dental schools as does the set-up of the outreach facilities. Table 1.1 outlines the current dental outreach teaching within UK dental schools. (QMUL 2014; University of Bristol 2014; University of Leeds 2014; University of Liverpool 2014 ; University of Newcastle 2014; University of Plymouth 2014; University of Birmingham 2014; UCLAN 2014; University of Manchester 2014; University of Sheffield 2014; Queens University Belfast 2014; University of Cardiff 2014; University of Aberdeen 2014; University of Glasgow 2014; University of Dundee 2014)

Table 1.1: Summary of Dental Outreach Delivery in the UK in 2014

UK Dental School	Outreach teaching summary
Barts and The London	Earliest attachments out of all the dental schools, with attachments to locally placed dental outreach clinics in their 3 rd year. Attachments further afield in 4 th and final years of the course
University of Bristol Dental School	Final year attachments to purpose built community hospital with 20 dental chairs (4 private surgery: 16 open plan)
Leeds Dental Institute	Attachments at the end of 4 th year and during final year. Three locations, students attend one day a week changing location each term.
Liverpool University Dental Hospital and School of Dentistry	Attachments within the final year to CDS in distance locations. Additional attachments to Personal Dental Service (PDS) practice. A total of 21 different practices are used for the 20 days of placements.
Newcastle Dental School	Students attend outreach placements in 4 th and final year.
Plymouth University (Peninsula)	Clinical teaching delivered in different locations with general dental practice attachments under development throughout the course.
University of Birmingham	Placements start at the end of 4 th year and continue through final year. Community clinic style attachments.
University of Central Lancashire (UCLan)	Final year attachments to 'Enhanced Training Practices' (purpose built outreach style clinics) located close to one of four 'Dental Education Centres'.
University of Manchester	10 outreach clinics SDS 4 th BDS
University of Sheffield	Students spend 20 weeks in two or three different outreach placements towards the end of their training. Placements are both in general practices and CDS.
Queens University Belfast	Students gain experience in restorative outreach clinics. Currently 7 sessions in their final year. This is being expanded at present.
Cardiff University	Final year attachments to community dental clinics and a dental care unit remote from the dental school.
Aberdeen Dental School	Students attend outreach attachments in years 3 rd and 4 th (final year of 4 year graduate entry course) in two purpose built outreach/SDS clinics.
Glasgow Dental School	47 outreach chairs in community health centres (SDS), in the final year.
University of Dundee	Final few weeks of 4 th year and final year attachments to six outreach clinics based within the SDS.

All dental schools in the UK currently deliver outreach teaching. The delivery of this outreach training varies between dental schools. The newer schools, Plymouth and UCLAN deliver their teaching within primary care environments across their courses, essentially delivering a form of outreach teaching throughout all years. Barts and The London Dental School place students in local outreach attachments in the 3rd year of their course, sending them to more distant locations in their 4th year. The majority of dental schools deliver outreach teaching in the fourth and final years of their courses. Sheffield dental undergraduates attend outreach from the end of their fourth year and during their final year. They attend a total of 20 weeks of general practice placements, and during this time complete outreach projects such as case studies, audit projects and teamwork projects (Smith et al. 2010). The majority of dental schools organise outreach attachments through the SDS, which may be in purpose built clinics or attachments to existing dental facilities. Within all attachments students deliver primary dental care.

The function of these dental outreach clinics within dental education is to ease the transition between hospital dentistry and general dental practice, so undergraduates have been in a primary care dental environment prior to graduation. These clinics afford undergraduates the opportunity to treat ‘general practice’ type dental patients with primary dental disease which they do not get experience of within the dental hospital/school clinics (Scottish Government 2004).

In Scotland, dental outreach has an additional function which is to provide access to dental care for local communities whom have previously struggled to attract dentists to their area and, as a result, have high numbers of unregistered patients (Scottish Government 2004).

The functions of modern dental outreach clinics in Scotland are further discussed in Section 1.4.2, under the Dental Action Plan.

1.4 Dental Outreach at University of Dundee

1.4.1 History of Dental Outreach at the University of Dundee

Historically, dental outreach at the University of Dundee formed a very small component of the undergraduate dental curriculum. Dental undergraduates attended attachments within the community dental services across Tayside during the 1980’s and 1990’s. On these attachments, students observed the work of the community dental service as they shadowed dentists carrying out provision of care including school screenings and visits to nursing homes and hospitals. Undergraduates also had opportunity to assist in the treatment of child dental patients and those with special needs. The aim of these outreach attachments was not to consolidate the students’ skills but to increase awareness of the dental services available outside of the dental hospital environment.

In the year 2000, a pilot group of ten, final year students were selected to attend what was, at the time, an enhanced form of dental outreach. This clinical attachment was designed to allow students to carry out dental treatment for patients outside of

Dundee Dental Hospital for the first time. The attachments were to general dental practices in the area as well as local community clinics. GDPs agreed to be involved in the pilot scheme and were paid a sessional rate for their time. The GDPs attended a training session and thereafter set up suitable patient lists for the student sessions. GDPs supervised the students' work on their own patients within their general dental practices.

This pilot was a success and both the practitioners and the students were positive about their experiences. Most importantly, there were no patient complaints. Patients were happy with the students carrying out treatment and the students were able to provide care to the required standard. The GDPs were positive regarding the professionalism and the skills of the undergraduates.

Although this pilot scheme was not rolled out further at that time due to funding, it had gathered vital information in relation to the students providing patient care out with the hospital environment. It determined that students could gain much more experience from this enhanced and more involved form of outreach than they had been able to from the shadowing style attachments. It was also observed that general practice dentists could successfully supervise dental treatment by students out with the dental school.

In 2003, shortly after this pilot, the Community Dental Service was developing into the Salaried Dental Service (SDS). The new SDS was tasked with expanding its remit to provide increased access to dental care within local communities and to provide emergency care for unregistered patients.

The recommendation that dental schools took measures to prepare undergraduates for primary care dentistry was formally put to the schools in the General Dental Council (GDC) document "The First Five Years" (GDC 2002). This document, combined with the later Scottish Dental Action Plan (Scottish Executive 2005) (section 1.4.2) gave rise to changes in dental outreach in Scotland which would increase the importance of clinical attachments out-with the hospital, cementing the place of outreach teaching in the curriculum.

During 2004, the University of Dundee, in a joint initiative with the SDS set up two pilot outreach chairs in the new Springfield dental clinic in Arbroath. These two chairs were gifted from the conservation department of the Dundee Dental School and the SDS arranged for installation. The use of these chairs was to be split between dental students on outreach attachments and the SDS. This initial set-up was achieved through goodwill and cooperation between NHS Tayside and the University of Dundee. Students at the clinic would see a designated book of patients while working under the supervision of the salaried dental staff.

The subsequent publication of the Scottish Dental Action Plan (Scottish Executive 2005) led to the provision of extensive funding which became available to support outreach between 2005 and 2011.

1.4.2 The Dental Action Plan

In 2005 the Scottish Government published a directive which was to shape the provision of dentistry within Scotland. The Dental Action Plan (Scottish Executive 2005) brought funding to salaried dental services and gave rise to rapid changes which were not only to improve the accessibility of dental care but also to shape dental education provision within Scotland.

The Dental Action Plan recognised that there were areas of dental need, where local populations had difficulty in registering with an NHS dentist. These were often in remote and rural locations or in areas of social deprivation. The plan provided funding for the SDS to improve their services including the building of new access clinics. This expansion of the SDS helped address the clinical space pressures which were present in the two dental schools (Dundee and Glasgow). At that time, both schools were registering greater numbers of dental students than they had clinical space for and since both were located in city centres there was little space for further expansion to accommodate extra dental chairs.

The Dental Action Plan (Scottish Executive 2005) followed the General Dental Council (GDC) guidelines for dental education: The First Five Years (GDC 2002).

The GDC recommended in this guidance document that undergraduates be given the opportunity to gain first-hand experience of primary care dentistry. This was to prepare them for their future careers as GDCs. The two documents together brought rapid changes to the dental curriculum, allowing students to spend a larger proportion of time delivering dentistry within primary care, in the new outreach clinics.

The plan also provided funding to allow Dundee, Glasgow and the new Aberdeen dental school to use purpose built outreach clinics in which undergraduates would supplement their clinical experience. The funding also allowed expansion of the original pilot clinic in Arbroath and the construction of a further six outreach clinics for use by The University of Dundee dental students. New clinics for Glasgow and Aberdeen Universities would result in a total of 17 outreach centres across Scotland.

These outreach clinics piggy-backed onto the new and existing Salaried Dental Service clinics which were positioned in areas of high dental need. Senior Dental Officers and designated dental outreach nurses were appointed to support the students in these facilities. The clinics were either built in brand new centres, such as Kings Cross, Dundee, or made use of existing buildings, such as in Kirkcaldy. This provided variation in the accommodation with some housing independent chairs and others working in a modern open plan environment similar to the dental hospital.

This expansion of dental outreach facilities enabled the dental curriculum to increase the student primary dental care experience. In Dundee this increased the time spent out of the dental school from 5 days in the academic year 1999/2000 to the 64 days in the final year 2010/11. Outreach was further extended to fill the final weeks of fourth BDS and immediately prior to final year, giving a further six weeks of experience in primary care. This extended outreach facilitated smoother integration between these years.

Outreach clinics were to provide dental treatment for unregistered patients. It was additionally hoped that not only would the undergraduates receive more experience of primary care dentistry but, by bringing undergraduates into remote and rural

areas, they would look further afield when applying for training positions and thereafter in their future careers, thus reducing the problem of dental recruitment to remote and rural areas in the longer term.

1.4.3 Dental Care Delivered in Outreach

Dental outreach clinics aim to provide increased experience of primary care dentistry to dental students, and as such, students attending the clinics deliver the full complement of primary dental care for their patients. The numbers of clinical procedures delivered by final year dental students from the University of Dundee during outreach attachments has increased year on year, for example: during the year 2009-2010 students delivered 38,000 procedures and this had increased to 49,631 procedures for the year 2011-2012 (Watt 2010, 2012). Dental outreach patients often have not received care for many years prior to attending the clinics, and the resulting high levels of primary dental disease makes them ideal as part of dental student training.

1.4.4 Current Dental Outreach Facilities Utilised by the University of Dundee

The outreach clinics utilised by the University of Dundee dental students are as follows:

Table 1.2: Layout and number of chairs in each of the dental outreach clinics attended by University of Dundee dental students

Clinic	Chairs	Layout
Arbroath	4	Independent surgeries
Aberdeen	8	2 Independent surgeries, 6 open plan
Cupar	3	Independent surgeries
Kings Cross	4	Open plan chairs
Kirkcaldy	3	Independent surgeries
Inverness	6	Open plan (shared with School of Therapy)
Perth	5	Independent surgeries

The large distance between the outreach clinics results in the students attending block attachments of one week duration in the Inverness and Aberdeen outreach clinics, within the academic year. The other clinics are attended on a day release basis. Expenses incurred by students are paid by the university including for travel to and from the clinics and for accommodation during block attachments.

These outreach clinics book between four and six patients per chair per day for student clinics, with individual clinics deciding on appointment lengths. These busy clinics focus student skills on time management as well as consolidating their specific clinical skills.

1.5 Dental Outreach as a Potential Environment for Clinical Research

As a setting for primary care dentistry, dental outreach clinics could be a potentially suitable research environment. The clinics receive patients who have not been registered with a GDP for many years. Outreach patients have high levels of primary disease which would be beneficial for a range of clinical research studies investigating dental care. The students delivering the care are in the final stages of their training and not dissimilar to first year graduates in their skills set. The nature of the teaching environment within outreach means that work is overseen and coordinated by one or two members of staff per session. The outreach clinics have good relationships with the Dental School and thus academic and NHS collaborations are already in place. There are several outreach clinics which would offer the potential for multi-centre research studies involving entire year groups of dental students which could be expected to result in robust findings.

Outreach clinics may have the potential to overcome barriers to clinical research within general dental practice environments as identified by Hopper and Clarkson (Hopper et al. 2011; Clarkson 2004) are outlined in Table 1.3.

Table 1.3: Summary of literature relating to barriers to clinical research from the literature and how these may be overcome by clinical research in dental outreach clinics

Recognised barrier to clinical research	Facilitating factor within dental outreach
i. <i>“loss of clinical freedom and control”</i>	Dental students are used to working under the guidance of members of staff and are yet to have experienced full clinical freedom.
ii. <i>“financial loss.”</i>	Dental students do not gain financially from the items of care they provide.
iii. <i>“lack of time.”</i>	Dental students already take longer than GPs to complete treatments. Appointments in outreach are already longer than those in general dental practice. Students may have time to carry out clinical research.
iv. <i>“disruption to practice and workload”</i>	The focus of outreach is educational and as such research should not be considered as a disruption to workloads and minimum patient treatments per day.
v. <i>“lack of interest”</i>	Outreach staff are committed to education. Staff involved in outreach often have previous experience of research and many hold postgraduate qualifications. Clinical research could potentially interest outreach staff and add an extra dimension to the clinics.

1.5.1 What would make Clinical Research in Dental Outreach Feasible?

For clinical research studies in dental outreach to be feasible the following people, parties and bodies would have to be supportive of the research:

- i. Research authorities:
 - The University of Dundee as sponsor of the research
 - Regional Ethics Committee (REC) to approve the study design
 - NHS Research and Development to approve the study
- ii. Bodies supporting the clinics:
 - NHS management
 - NHS Education Scotland (NES)

The University of Dundee

iii. People delivering outreach:

Dental Outreach Staff

Dental Nurses

Final Year Dental Students

iv. Service users:

Dental Outreach Patients

1.5.2 Dental Outreach at the University of Dundee and Opportunity to Deliver Clinical Research

Dental outreach clinics could provide an opportunity to deliver clinical research studies in primary care. They may provide a solution to the challenge of recruiting practitioners to primary care research on two levels:

- the clinics themselves provide a primary care environment in which clinical research studies could be delivered;
- including involvement in clinical research in the undergraduate curriculum provides an opportunity for undergraduates to gain first-hand experience of carrying out clinical research in a primary care environment. This could generate future interest in involvement in research studies upon graduation.

At the University of Dundee dental students attend outreach attachments at the end of fourth and during their final years. This ensures that their clinical skills are well established and outreach attachments provide a consolidation of these skills. This would ensure that undergraduates carrying out clinical research in outreach at the University of Dundee would have the necessary practical skills required of a clinical study. There are 7 outreach locations which would provide a good geographic and demographic spread of patients. The number of students in the final year (around 70) and the many outreach supervisors would potentially provide robust results, akin to having many general practitioners carrying out the research. The links to the University of Dundee could provide outreach clinics with the necessary academic support for a clinical research study.

These attributes and the teaching environment could provide a new environment in which to deliver clinical dental research studies. The literature review in Chapter 2 will examine research studies carried out within dental outreach clinics to date in order to help develop ideas for research at Dundee Dental School outreach clinics.

Chapter 2: Literature Review

2.1 Introduction

This thesis aims to investigate the feasibility of clinical research in dental outreach clinics. This literature review aims to identify and discuss existing clinical research studies carried out within undergraduate dental outreach clinics. The following areas are addressed:

- Dental outreach terminology (2.1.1)
- Methodology for literature searching (2.1.2)
- Search results (2.2)
- Review of literature from the search results (2.3)

2.1.1 Dental Outreach Terminology

Dental students have attended clinical attachments outside of teaching hospitals since 1977 (Holloway & Dixon 1977). The term ‘dental outreach’ can be applied to any dental education activities out with the dental hospital environment, as defined by Eaton:

“Teaching which although co-ordinated by a traditional provider of dental education, such as a dental school, takes place at a site distant to the traditional centre” (Eaton et al. 2006)

Although the term ‘dental outreach’ is nowadays mostly used to describe dental undergraduates providing care in dedicated teaching facilities out with the hospital, the term may also be applied to undergraduate activities such as observing visits to schools, prisons or nursing homes (Elkind 2002; Watson et al. 2007), in addition to attachments to primary care clinics. Such clinics may be existing or purpose built premises and be situated within the salaried dental services or general dental services. The term ‘dental outreach’ has additionally been used to describe qualified

dentists providing a service to communities who struggle to access dental care (Cure & Ireland 2008) For the purposes of this literature review the term ‘dental outreach’ will be defined as:

“Dental undergraduates delivering clinical dentistry in a primary care location out with the dental school environment”

Such locations have evolved since that first hospital annex model (Holloway and Dixon 1977) and now various models are employed by dental schools within the UK. There is a consistent model for dental outreach across Scotland which was developed through a collaborations between NHS Education for Scotland (NES), the University Dental Schools (Dundee, Glasgow and Aberdeen) and the salaried dental service.

At the University of Dundee, dental undergraduates provide outreach dental treatment at clinics which are situated within the salaried dental service. These clinics include both purpose built and existing salaried dental premises. Dundee undergraduates are timetabled to attend these attachments both daily and in block attachments, depending on the proximity of the clinic to the dental school. This arrangement of dental outreach attachments within the salaried services, is also utilised by the other UK dental schools (Craddock 2008; Smith et al. 2010; Smith et al. 2011). Additional dental outreach arrangements have included the provision of dental care by undergraduates in surgeries situated within general dental practices (Cheshire 2002), and undergraduates attending community attachments to increase their experience in specific areas of dental care such as paediatric dentistry as utilised in Manchester and Liverpool (Elkind 2002). Dundee undergraduates additionally attend outreach attachments to increase experience of oral surgery, however these attachments are generally out with the general outreach scheme at Dundee University Dental School and take place within a secondary care setting which may exist in premises normally used for primary care. Many of the schools in the UK combine arrangements for outreach provision.

In addition to the above described outreach attachments, dental undergraduates may attend attachments in which to observe, rather than provide, dental care. These attachments include visits to schools, nursing homes, hospitals, prisons, and general practices (Elkind 2002; Watson et al. 2007).

2.2 Methodology for Literature Search

The different outreach settings were considered and taken as initial points for this literature search. Dental hygiene and therapy students have attended outreach attachments and therefore this group of students was included in the search criteria. In the United States, outreach attachments are referred to as ‘Extra-mural’ attachments and as such the terms ‘outreach’ and extra-mural’ were considered synonymous. The following additional terms were also included in literature search: Outreach, community, primary care, extra-mural, dental, therapy, hygiene, and student. These were then expanded through snowballing (using the references from the initially identified outreach papers) to include the additional terms: ‘pipeline programme’ (a U.S project involving outreach to the community), ‘undergraduates’, ‘attachment’, and ‘placement’.

Advice was taken from contacts within the Cochrane collaboration on construction of the literature searches. When examining the initial papers, many referred to programmes which involved provision of dentistry to specific groups in the community who may not otherwise be able to access dental care. The majority of these programmes did not involve dental students. The terms ‘student’, ‘undergraduate or ‘education’ were emphasised in the structure of the search. The following keywords were then utilised for the literature searches:

- community
- outreach
- extra-mural
- pipeline programme
- education
- dental

- students
- undergraduate
- dentist
- therapist
- hygienist
- clinical
- dentistry

The search structures can be found in Appendix 1.

Searches were completed in Medline, Embase, Cochrane and Cinahl databases, yielding 168, 104, 2 and 60 papers, respectively.

Titles and abstracts were read and scrutinised for relevance. In order to be considered relevant to this thesis, a reference had to relate to clinical research studies in dental outreach clinics involving either dental students, dental therapy students or dental hygiene students. Papers were obtained for closer inspection where there was uncertainty of the relevance of the paper from the abstract. Dental outreach papers which were considered relevant to this thesis had their references examined to identify any further relevant papers.

The literature search was conducted initially in August 2009, prior to setting up the Dental Outreach Oral Hygiene Study, and updated in March 2012 (Appendix 1). These literature searches were then updated further in August 2017 to capture any additional relevant dental outreach papers prior to submission of this thesis. This process identified one additional relevant reference. This additional paper is included at the end of this review.

2.3 Search Results

The literature search results and the main findings from each paper are tabulated in Appendix 2. Figure 2.1 displays the reasons why papers identified by the literature searches were excluded:

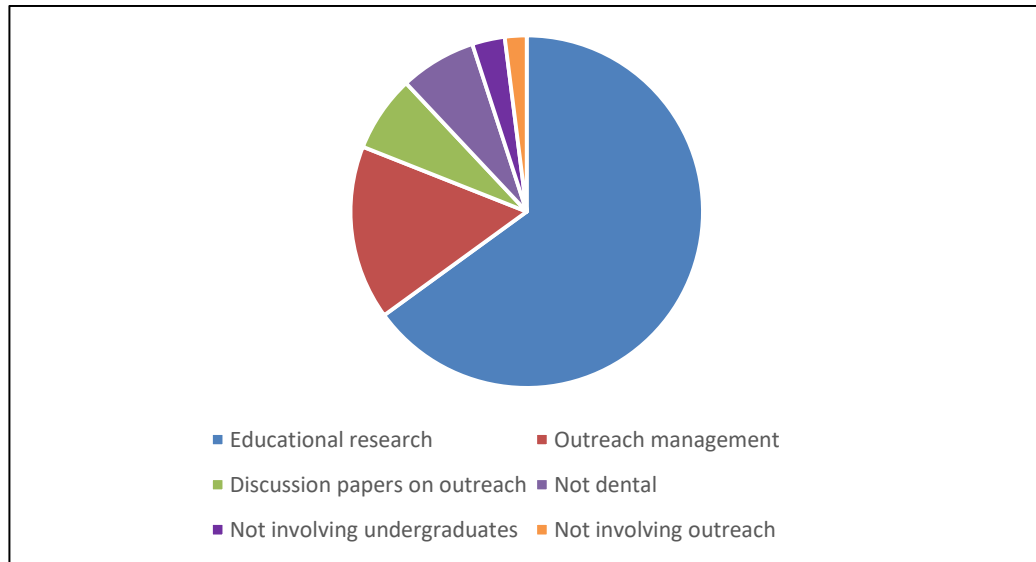


Figure 2.1 Reasons dental outreach papers identified by the searches were subsequently excluded as not relevant to the topic of clinical research in dental outreach, by proportion

The literature searches found no publications relating specifically to clinical research studies carried out in undergraduate dental outreach clinics. Additional dental outreach literature published between 2012 and 2017 was searched during August 2017, this search identified further educational outreach papers and one paper (Conway et al. 2016) which detailed the use of outreach patients to gather data in a pilot research study investigating HPV. In this pilot research nurses, not dental undergraduates, collected the research data.

The review will initially discuss the dental outreach literature identified prior to more in-depth searching.

2.4 Literature Review

The first dental outreach publication (Holloway and Dixon, 1977) discussed the educational benefits of dental outreach clinics - improving undergraduate awareness of patients' social circumstances, undergraduate understanding of primary care dentistry, and increasing their breadth of clinical experience (Chapter 1.3.1). Over the following two decades there was very little published literature regarding dental outreach.

In the early 2000's there was a resurgence of interest in dental outreach, both in the UK and the US. This renewed interest in dental outreach, and the resulting publications, were due to two events. In the UK, the GDC published their second edition of *The First Five Years* (GDC 2002), which gave guidance to dental school curricula - that dental undergraduates should gain experience of primary care dentistry. In the US a large multi-state extra-mural initiative was launched involving dental schools - the 'Pipeline Project'. These events are discussed in further detail subsequently.

The First Five Years emphasised dental outreach as an important aspect of the undergraduate curriculum (Clark et al. 2003). This resulted in an increased commitment to dental outreach by the UK dental schools and often the building of dedicated outreach facilities. Within Scotland, the Dental Action Plan (Scottish Executive 2005) further cemented this commitment to outreach; the building of new outreach facilities would improve access to NHS dental care in communities which had struggled to recruit NHS general dental practitioners. The Action Plan suggested that outreach teaching facilities should be built in such community areas.

The dental outreach publications to date are mostly educational in basis and have investigated benefits of dental outreach education to dental students (Kerosue et al. 2001; DeAngelis & Warren 2001; Seymour & Walsh 2001; Ayres et al. 2001, 2005; Formicola et al. 2002, 2012; Elkind 2002, 2005, 2005, 2007; Bartlett & Woolford 2003; Sanders & Ferrillo 2003; Mofidi et al. 2003; deCastro et al. 2003, 2005; Chavez & LaBarre 2004; Woronuk et al. 2004; Thind et al. 2005, 2009; Eaton

et al. 2006; Smith et al. 2006, 2006, 2006, 2009, 2010, 2010, 2011; Baumeister et al. 2007; Hunter et al. 2007; Lloyd 2007; Mascarenhas et al. 2007, 2011, 2011; Kuthy et al. 2007, 2010; Nitschke et al. 2008; McQuistan et al. 2008 2010; Craddock 2008, 2011; Hind et al. 2009; Abuzar et al. 2009; Maguire et al. 2009; Lynch et al. 2009, 2010, 2010, 2010, 2010, 2011, 2011; Martin et al. 2010; Haden et al. 2010; Hewlett et al. 2009; Hunter & Chaudhry 2009; Perez et al. 2010; Rodd et al. 2010; Holmes et al. 2011; Huggett et al. 2011; Eriksen et al. 2011; Andersen et al. 2011; Arevalo et al. 2011; Atchison et al. 2011; Johnson et al. 2012; Cure 2009; Daher et al. 2012; Piskorowski et al. 2012; Taichman 2012; Radford & Weld 2013; Radford et al. 2014, 2015; Radford & Hellyer 2015, 2016, 2017; Joury 2016).

Other dental outreach publications discuss the set up and management of dental outreach clinics or benefits to the health services (Cinotti et al. 1999; Bailit et al. 1999, 2005, 2007, 2009, 2010, 2011; Lennon 2007; Waterhouse et al. 2008; Atchison et al. 2009; Colangelo 2009; Hewlett et al. 2009; Hind et al. 2009; Thind et al. 2009; Mascarenhas & Henshaw 2010; Smith et al. 2010; Piskorowski et al. 2011; Bean 2011).

2.4.1 Dental Outreach and Education Research

This review will now discuss further the dental outreach educational research.

Dental outreach educational research has primarily focused on the benefits of extramural attachments to dental students.

Dental outreach attachments have been used to provide an overall widened experience of dental care for undergraduates when compared to their experience within the dental school environment. This widening of experience extends into many aspects of their dentistry. This has been measured both by structured questionnaire and focus groups over the years. (Heitke 1984; Ayers et al. 2001; Chavez & LaBarre 2004; Elkind et al. 2005; Mascarenhas et al. 2007; Bailit et al. 2010; Bailit et al. 2010; Lynch et al. 2010; Lynch et al. 2010; Martin et al. 2010; Eriksen et al. 2011; Lynch et al. 2011). Additionally, the numbers of procedures

undergraduates complete in outreach form general reports as required by financial investors such as NES (Watt 2010, 2012, 2014) This outreach experience has been reported to be improved further when working with dental nurses on a one-to-one basis, rather than in student pairs (Martin et al. 2010).

Outreach attachments are also utilised by dental schools in order to give undergraduates further experience in particular areas of dentistry which have been difficult to achieve within a dental hospital environment such as paediatric dentistry (Bohaty et al. 1992; Hewlett et al. 2009; Hunter & Chaudhry 2009; Rodd et al. 2010). Outreach attachments have also been used to expose dental students to more diverse patient groups as the hospital environment often sees a fairly homogenous patient pool (Elkind 2002; Andersen et al. 2005). Attachments have additionally been used to gain further experience of restorative dentistry (Watson et al. 2007),

With the increase in experience of patient care in dental outreach there has been much research looking into the effects of these placements on the dental students. The evidence is that outreach teaching is beneficial for undergraduates. There is a reported increase in skills and competency of dental undergraduates after attending outreach attachments (Butters & Vaught 1999; DeAngelis & Warren 2001; DeCastro et al. 2005; Elkind et al. 2005; Mascarenhas 2007, 2011; Hewlett et al. 2009; Berg et al. 2010; Holmes et al. 2011; Lynch et al. 2011; Smith et al. 2011; Radford & Weld 2013; Joury 2016). These attachments have been used to give undergraduates specific skills in areas such as audit (Lynch et al. 2011; Radford & Weld 2013) but no studies have been published involving undergraduates in clinical research studies in an outreach setting.

The productivity of dental undergraduates attending outreach attachments, as measured by the number of procedures, has been shown to increase in dental outreach attachments in comparison with dental school/hospital experience. This experience is greater for simple, general practice dental treatments (Ayers et al. 2001; Woronuk et al. 2004; DeCastro et al. 2005; Bean et al. 2007; Mascarenhas et al. 2007; Maguire et al. 2009; Bailit et al. 2010; Perez et al. 2010; Arevalo et al. 2011; Eriksen et al. 2011). This experience of simple primary care procedures is one

of the main reasons for sending dental undergraduates out with the hospital environment.

In addition to the development of manual dental skills, undergraduates attending outreach programmes/attachments are reported to gain in personal attributes such as confidence (Mofidi et al. 2003; Elkind et al. 2005; Smith et al. 2006; Hunter et al. 2007; Mascarenhas 2007, 2011; Hind et al. 2009; Maguire et al. 2009; Lynch CD, et al. 2010, 2011; Daher, et al. 2012; Walley et al. 2014; Radford et al. 2015, 2017). Such confidence helps to prepare them for general dental practice (Lynch et al. 2011; Radford et al. 2015), easing the transition to vocational training schemes. More recently additional educational aspects of the undergraduate experience in outreach such as empowerment have been explored (Radford & Hellyer, 2016) in the dental outreach setting.

When compared to the dental hospital undergraduate clinics, dental outreach clinics are found to be busier, with a pace of patient throughput more akin to general practice. This pace of practice improves dental undergraduate time management skills (Elkind 2002; Elkind et al. 2005; Mascarenhas 2007, 2011; Craddock 2008), which is essential for developing dentists.

Students attending attachments out with the dental schools work in dental teams. This may include one-to-one nursing support, something which they do not often have the luxury of in the hospital environment. This increased support is essential for the busy clinics and has been shown to improve student team working with dental nurses (Bartlett & Woolford 2003; Craddock 2011; Elkind 2002; Kerosuo et al. 2001; Lynch et al. 2010; Smith et al. 2006, 2011). Working in such a team improves communication skills (Blinkhorn 2002; Elkind 2002, 2005). Additionally, leadership has been demonstrated to improve with outreach teaching (Taichman 2012).

Dental undergraduates attending outreach work within the public dental service (Elkind 2002; Ayers et al. 2003; Kassebaum 2004; Elkind et al. 2005; Cure 2009; Atchison et al. 2011, Bean 2011) gain experience in specific community areas e.g.

rural environments where they treat a more diverse population than they would experience in the hospital setting (Mofidi et al. 2003; Thind et al. 2005; Kuthy et al. 2007; Zoitopoulos et al. 2007; Craddock 2008; Abuzar et al. 2009; Hewlett et al. 2009; Kuthy et al. 2010). Students in outreach may treat vulnerable populations, such as special needs patients (Kuthy et al. 2007). Providing care for such patients has been shown to improve empathy in dental students (Mofidi et al. 2003). Attending outreach attachments within the community and treating vulnerable patient groups has been proven to increase maturity and improve attitudes in undergraduates (Kerosuo et al. 2001; DeCastro et al. 2003; Baumeister et al. 2007; Eriksen et al. 2011; Joury 2016; Radford & Hellyer 2017). Outreach experience has also been reported to increase social responsibility and professionalism in dental students (Thind et al. 2005; Lloyd 2007; Holmes et al. 2011).

Other educational research identifies outreach attachments to be important in encouraging pursuit of academic careers (Elkind 2002; Aggarwal et al. 2011) and careers within the public dental service (Abazar et al. 2009).

There have been no reported disadvantages to dental students of including dental outreach in the curriculum. The management side of dental outreach has however been reported to be challenging (Elkind et al. 2007).

Dental outreach clinics are now usually set up within the salaried dental service. They are situated in areas where it has been traditionally difficult to recruit dentists. This is the case both in the U.K through the NHS, and US, through the Pipeline programme. Establishing clinics in such areas improves access for patient groups (Bailit et al. 2005; Elkind et al. 2005; Elkind et al. 2006; Lloyd 2007; Bailit et al. 2010; Strauss et al. 2010; Mascarenhas 2011).

The general set up and development of dental outreach clinics has been discussed (Lekic et al. 2000; Lennon 2007; Waterhouse et al. 2008; Hind et al. 2009; Smith et al. 2010; Piskorowski et al. 2011). Setting up and managing such clinics involves collaboration, and in the UK, shared finance between the Universities and the NHS. Some of the additional difficulties in outreach development include organization of

staff training. The clinics may be situated in different cities to the dental school hub. Communication between outreach clinics and the dental schools is essential to the smooth running of such facilities. This is especially vital with regards to timetabling of dental students and in maintaining quality of outreach teaching (Hind et al. 2009).

2.5 Literature Review Conclusion

The literature searches conducted prior to the Dental Outreach Oral Hygiene Study found there to have been no clinical research studies carried out within undergraduate dental outreach clinics. This gap in the literature regarding clinical research in dental outreach therefore makes the feasibility of clinical research in dental outreach clinics a suitable subject area for study.

Searching identified one relevant reference concerning clinical research in dental outreach clinics (Conway et al 2016). This paper discusses a pilot study investigating the feasibility of a further population investigation into the Human Papilloma Virus. Conway's group utilised dental outreach clinics for the recruitment of patients to their pilot study. This was in addition to patients from general practices. The recruitment of outreach patients in this pilot study was however undertaken by research dental nurses, not dental undergraduates.

The educational benefits of dental outreach continue to be the mainstay of research carried out in the dental outreach clinics.

There have, to the author's knowledge, been no prospective clinical studies undertaken by dental undergraduates in outreach clinics apart from the author's study as discussed in this thesis.

Chapter 3: Aims of this Research

This chapter outlines the aims and the structure that this research took. It maps the chapters which follow.

The overall aim of this thesis is to investigate the feasibility of clinical research in the dental outreach environment. This investigation is undertaken through the identification of barriers against and facilitators towards clinical research in this environment. Additionally through this process, the advantages and disadvantages of clinical research in dental outreach will be identified. This will be achieved by utilising a previously proven primary care clinical research model and delivering this within the dental outreach clinic environment thus testing the suitability of this environment in supporting clinical research.

Prior to choosing a suitable clinical research study existing views towards clinical research in dental outreach will be explored (Section 4). This will involve:

- Semi-structured interviews with outreach management stakeholders (Section 4.1)
- Focus group with final year dental students (Section 4.2)
- Workshops with outreach staff (Section 4.3)

From this pre-study exploration, views will be identified. These views will feed forward and assist in identifying a suitable clinical research area for dental outreach clinics. The Dental Outreach Oral Hygiene Study (DOOHS) development is discussed in Chapter 5:

- The choice of research topic and thereafter identification of the previously tested research model suitable for piloting within the dental outreach environment is discussed in Section 5.1
- The development and finalised design of DOOHS is discussed in Section 5.2
- Paperwork development is discussed in Section 5.3

- Necessary permissions required for delivering clinical studies in dental outreach are identified and the practicalities of achieving these permissions are discussed in Section 5.4

The delivery of any clinical research study requires training. For clinical research studies in dental outreach both dental students delivering clinical research in dental outreach and the dental outreach staff responsible for supervising research delivery on the clinics require training. Chapter 6 discusses training for the Dental Outreach Oral Hygiene Study.

The implementation of the Dental Outreach Oral Hygiene Study is covered in Chapter 7. Issues in delivering research in outreach, in particular with regards to recruiting (Section 7.1) and reviewing participants for studies in dental outreach are explored.

The results of the Dental Outreach Oral Hygiene Study are covered in Chapter 8.

Chapter 9 explores post-study views of outreach staff, final year students' and DOOHS participants on clinical research in dental outreach. This is achieved through:

- The implementation of questionnaires to final year dental students (Section 9.1)
- Conducting post-study focus groups with final year dental students (Section 9.2)
- The implementation of questionnaires to outreach staff (Section 9.3) and,
- Post-study outreach participant questionnaires taken at review visits for DOOHS (Section 9.4)

The discussion (Chapter 10) and Conclusions (Chapter 11) follow.

Chapter 4: Exploration of Existing Views on Clinical Research in Dental Outreach

During the pre-study exploration, outreach management stakeholders, final year dental students and dental outreach staff were consulted to explore existing views around the topic of clinical research in dental outreach. This was achieved through:

- interviews with outreach management stakeholders;
- focus groups with final year students; and
- workshops with outreach staff.

4.1 Outreach Management Stakeholder Semi-Structured Interviews

4.1.1 Semi-Structured Interview Objectives

i) The objectives of interviewing the outreach management stakeholders were to explore their existing views on:

- The topic of clinical research in dental outreach
- Barriers and facilitators to clinical research in the dental outreach clinics
- Potential advantages and disadvantages of clinical research for the groups involved

ii) And thereafter:

- Establish the concurrence and divergence of views through triangulation with the stakeholder responses and those of the outreach clinic staff and final year students

4.1.2 Semi-Structured Interview Methodology

To elicit the views of the management stakeholders, semi-structured interviews were chosen as the most appropriate qualitative research technique. Interviews were considered to be the best method of gaining a preliminary insight into views on clinical research in dental outreach.

This interview technique is traditionally used to generate themes on any given topic (Barbour 2008). For the purposes of this research, semi-structured interviews would generate data through exploration of the previously un-studied field of clinical research in the dental outreach clinic environment. The interviews were conducted face-to-face with each management stakeholder. Face-to-face interviewing was chosen over the possibility of conducting interviews by telephone in order to allow the body language of each interviewee to be taken into consideration (Barbour 2008). This also allowed the building of rapport and the conduction of questioning in a sensitive and appropriate manner. In turn, this maximised the depth of response from the interviewees.

Although there was standardisation of the interview process, following a schedule of questions; the freedom to explore each idea as fully as required, before moving on to the next interview question, was retained. This freedom to move off-script allowed for an increased depth of answers and opinions.

Semi-structured interviews have previously been utilised to explore themes within dental outreach research. This method of data generation was used by the University of Sheffield during their exploratory studies into the value and feasibility of dental outreach placements (Smith, Lennon et al. 2006). Smith's group triangulated the results of their semi-structured interviews with data generated through their focus group discussions investigating the dental outreach experience from their students' viewpoint.

Initially, the stakeholder management group (SGx) was identified. All participants were considered to hold relevant key managerial roles with regard to aspects of

outreach clinics. This group consisted of nine individuals, from both NHS and academic (AC_x) backgrounds and were chosen to give views from both academic and NHS perspectives. The group consisted of:

- Two Deans of dental schools (AC_{1,2})
- A senior academic responsible for outreach (AC₃)
- One NHS Education for Scotland academic (NES) with responsibility for funding for outreach and outreach development across Scotland. (AC₄)
- Four NHS clinical directors, one from each health board with outreach clinics attended by University of Dundee dental students (NHS₁₋₄)
- A dental outreach supervisor with daily responsibility for patient treatment on outreach clinics (NHS₅)

Prior to conducting structured interviews the author undertook training in qualitative research methods. Each Stakeholder was contacted with information regarding the proposed research topic and consent from each Stakeholder was granted by email. Suitable interview times were arranged and the interviews were carried out over a six week period. At the meeting, the interview process was explained verbally and consent was re-confirmed. Interviews took place in stakeholders' offices at a time convenient to them. The interviews were digitally recorded, with the permission of each interviewee. A copy of the recording was emailed to the interviewee if requested. In addition to digital recordings, notes were taken at the time of the interview to record any body language and gestures. Additionally the overall tone of the interview (positive/neutral/negative) was noted.

Each stakeholder was questioned using the standardised interview schedule (Appendix 3). The interview questions were designed to explore views around the topic of clinical research in dental outreach and were organised to reflect directly the outlined research aims. The interview schedule was designed to gain the following information:

- Demographics of the stakeholders:
 - Role in outreach

- Length of time they had been involved in outreach
- Previous research experience
- Management stakeholder views on suitable topics for:
 - Clinical research, in general
 - Clinical research, specifically regarding the dental outreach environment
- Management stakeholder views on:
 - Potential advantages and disadvantages they considered clinical research in outreach clinics could bring to the groups involved
 - Barriers and facilitators to clinical research within the outreach clinics

Care was taken to deliver each interview in the same manner. Questions were clarified if required and it was ensured that the interviewee was not led in any way. If the interviewee happened to provide the answer to a later question in response to an earlier one, the question was reposed at the allocated point in the schedule in order to clarify the answer. No time restraints were placed on the interviews and thus they varied in length, the shortest being 15 minutes to the longest which was 45 minutes. The time was dependent on the fullness of responses given and depth of opinion for each question. In this way the data gathered was as full and detailed as possible. Where questions were avoided by the interviewee, these were reposed later in the schedule. However, if the particular question was subsequently evaded again or the interviewee made it clear they did not wish to answer the question, it was dropped in order to continue the interview on good terms. Answers were expanded as far as each interviewee wished during the process.

4.1.3 Methodology of Analysis

Prior to analysing results the author had attended training in qualitative research analysis. Advice was sought, where required, during this course. Transcriptions of the interview recordings were completed as close to the time of the interview as possible, usually the following day. Transcripts from the structured interview recordings underwent thematic analysis (Barbour 2008). As with all qualitative analysis, thematic analysis is dependent on familiarity with the data (Braun & Clarke

2006) and for this reason the interviews and coding were completed by the author. Open coding of these transcripts was completed by hand to identify key themes which were organised through data extraction tables (Barbour 2008). The themes identified were reassessed alongside the original interview recordings and interview notes.

Content analysis was carried out on the transcripts (Bowling 2009). This process of analysis involves the coding of each transcript line by line into themes (Barbour 2008). After analysis of the content, transcripts were next re-examined with the digital interview recordings and notes taken at the time of interview to assess reliability of the themes. Themes emerging from the transcripts were identified through the content analysis tables generated from the transcripts. Figure 4.1 gives an example of a Coded Transcript:

Any disadvantages for the patients involved?

Some of the patients might feel there's too much time being spent doing talking and not enough actually doing. 'I came in here to get my teeth extracted or my fillings done, or my teeth polished; I didn't come in to have you talking at me for this that and the other. I think the sum of those patients will be small as I think the majority of patients in Outreach are delighted to be being treated, getting dental treatment anyway. And, you might actually exclude those patients anyway, because, certainly up here, we have an assessment process prior to the patients coming in...they're screened before they?...yes we screen them before they come in to make sure they are acceptable to the students at that level of their education and also that they are willing to come in and be treated by students and to realise that the treatment will take longer. So I think what that tends to do will potentially remove some of your patients that might take the attitude I have just talked about. You are going to get a few of them but I think the pool of patients you see are likely to be quite happy to have an input into this.

Any disadvantages for the service?

(Pause) Well, that's an interesting one, because I think many of the health boards, NHS boards rather, look at this as a means of helping them reduce their NHS backlog lets say, and they might turn round and say 'if you're spending time doing this, the number of throughput of patients will go down'. I think the answer to that is that what we are endeavouring to do is to be able to provide a better level of care for the patients that come through. And make sure what you are doing for those

Example key for coding: Patient Altruism, Time, Service delivery threat, Service delivery advantage.

Figure 4.1: Example of Coding Transcripts for the Pre-Study Exploration

The themes generated through the semi-structured interviews additionally underwent triangulation with the findings from the preliminary student focus group (Chapter 4.2) and the outreach staff workshop groups (Chapter 4.3), in order to establish validity of the findings (Golafshani 2003).

4.2 Final Year Dental Student Focus Group

4.2.1 Focus Group Objectives

During this phase, final year dental students attending outreach clinics were consulted through the use of a focus group held in October of the final year. The objectives of this focus group were to specifically explore the students' existing views on:

- the topic of clinical research in dental outreach
- barriers and facilitators to clinical research in the dental outreach clinics
- potential advantages and disadvantages of clinical research for the groups involved

And thereafter:

- establish concurrence and divergence of views through triangulation with the stakeholder responses and those of the outreach clinic staff.

4.2.2 Focus Group Methodology

Initial consideration was given to eliciting student responses by means of structured interview, identical to those used for the management stakeholders. The use of semi-structured interviews in this case was however considered to be inappropriate as there was a potential conflict of interest due to the interviewer additionally holding the role of clinical supervisor to the students. It was considered that use of one-to-one interviews could potentially be seen as intimidating by students, especially at this

early stage of their final year. There was also concern that this conflict could potentially introduce bias, with students giving responses they considered to be 'correct' in order to win favour from the clinical supervisor/researcher.

In order to generate a depth of response on the topic of clinical research in dental outreach, focus groups were chosen as the most appropriate qualitative research method (Chestnutt 2001). Focus groups allow participants to discuss a set topic together and respond as a group. This removes the pressure from individuals. The use of focus groups in this case encouraged discussion on the given topic of clinical research in dental outreach. The data from the student focus group would be used to interpret results from the semi-structured interviews and the staff outreach day focus groups (Section 4.3) in order to triangulate the results and examine data validity (Stewart & Shamdasani 1990; Barbour 2007). The focus group discussion followed the structured interview question topics previously posed to the management stakeholders, but allowed the students to discuss thoughts and answer as a group.

During this period of research the author was responsible for clinical supervision of dental students during outreach attachments for one session per week at the Kings Cross Outreach Clinic in Dundee. It was during one of these sessions that the students were invited to discuss the topic as a group. This group were additionally joined by an outreach dental nurse. The nurse joining the group had considerable experience of supporting dental students in the outreach clinic as well as the type of patients who attended. She had expressed interest in the subject of clinical research in dental outreach and wished to participate in the group. The students present were simply selected by their availability at the time and their willingness to participate in the focus group. This particular student group had been working together in outreach for the three months prior to the discussion and had treated a variety of patients during this time in different outreach clinics. It was stressed to the students that their responses would be anonymous and would not prejudice any future grades. Thus, they were freely able to express their opinions without fear of penalty or impact on academic grades. The group gave consent for the recording and transcription of the discussion. Notes regarding the interaction between the students were taken alongside the recording.

The group consisted of three male dental students, one female dental student and a female dental nurse. All members of the group contributed and there was no particularly dominant member. The discussion took 20 minutes.

Transcription was completed by the author shortly after the discussion took place.

4.2.3 Methodology of Analysis

The student focus group transcript underwent thematic analysis and coding as per that carried out on the management stakeholder interview transcripts. Later the results were triangulated with results from other groups previously described in section 4.1.3.

4.3 Outreach Staff Outreach Training Day Workshop Groups

4.3.1 Workshop Groups Objectives

Dental outreach staff were consulted through workshop groups. The objectives of the workshop groups were to explore, pre-study, the existing views of dental outreach staff and to search for concurrence and divergence of themes with the management stakeholder and student views. This was completed using the same criteria as the management stakeholders and the final year students.

4.3.2 Workshop Groups Methodology

In order to collect the views of both nursing staff and outreach supervisors, the methods of structured interviews, focus groups and workshops were considered. Workshops were chosen to give the greatest potential to gather suggestions and generate themes, involving as many of the outreach staff as possible. Additionally, this would ensure the inclusivity of the research, not limiting data collection to specific chosen individuals or areas which may introduce bias into the data collected.

Workshops would also give staff from different outreach clinics opportunity to discuss ideas before generating a group opinion.

As the dental outreach clinics were geographically spread out, there was little opportunity to gather all outreach staff together during the year solely for the purpose of collecting data for the research. However, the University of Dundee hosted an annual training day for outreach staff. This included nursing staff and outreach supervisors, with additional attendance from some outreach managers. The purpose of the training day was to provide an opportunity for outreach staff from different areas to meet each other and discuss outreach teaching, updating outreach staff on aspects of teaching and training dental undergraduates. There were lectures and practical courses provided on aspects of clinical care. The day was very popular with the outreach staff and as a result was well attended. It was therefore decided to take the opportunity to use the annual dental outreach training day where all staff would be together in order to conduct the staff workshops.

The University of Dundee allowed use of one hour of time during the outreach teaching day in May 2010, during which time a short presentation and workshop groups were carried out.

The short presentation introduced the concept of clinical research in dental outreach to the outreach staff (Appendix 4). This presentation provided both an introduction to the idea of clinical research in dental outreach and the concept of evidence based dental care and professionalism. Furthermore, this presentation used audience participation via TurningPoint™. This tool was used to involve the group by making the presentation interactive and enabled the collection of demographics and general opinion.

After the presentation, the nursing staff and clinic supervisors were split into pre-allocated, mixed groups. These groups were designed to contain a balance of supervisors and nurses from clinics within the four Health Boards (Tayside, Fife, Highland and Grampian). It was hoped that this mixing of both staff type and location would encourage staff to discuss their opinions as freely as possible and

allow staff the opportunity to discuss the viewpoints coming from the different health boards. It was hoped that the mixed groups would draw on their experiences from each outreach clinic and facilitate discussion of local issues in addition to the common aspects of the clinics. In the interests of time, and to ensure equal consideration was given to each question, each staff group was asked to initially consider one of the questions which had been posed to the management and by the student focus group. The questions posed allowed opportunity for discussion of the perceived advantages and disadvantages of clinical research in dental outreach to dental students, outreach staff, and outreach patients. The groups also discussed the perceived barriers and facilitators to clinical research in the outreach clinics and potential solutions.

In order to collect responses, each group was given sticky notes to record their views and suggestions onto. These were attached by the groups to posters around the room relating to each of the topics considered (Figure 4.2). The movement within the room encouraged exchanges between the groups and kept the session informal. Themes emerging could easily be identified from the posters.

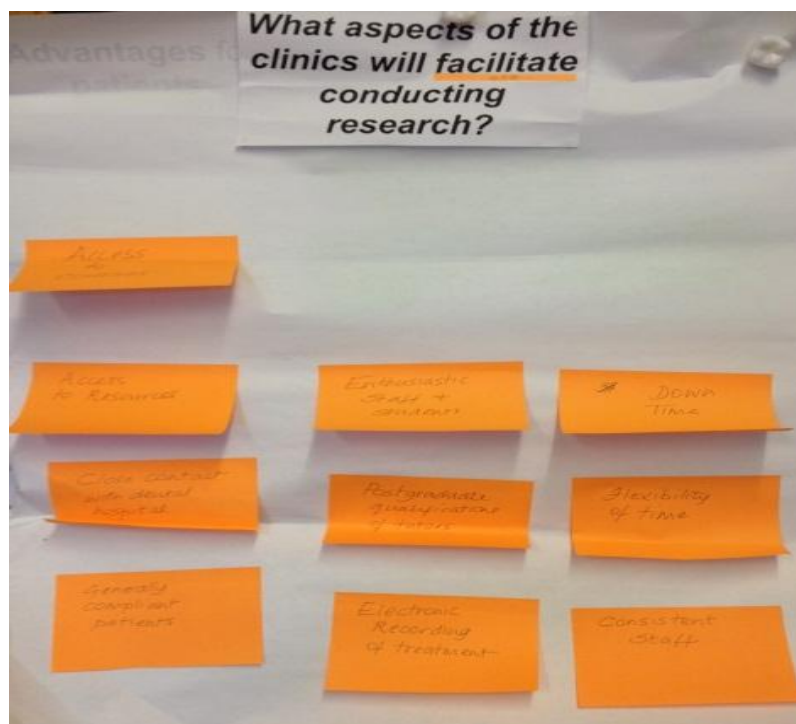


Figure 4.2: Example of poster produced during group workshop

In order to facilitate the discussion, a representative from Scottish Dental Practice Based Research Network (SDPBRN) was present to help with any specific clinical research based questions. The content of each group's discussion was summarised by the spokesperson for that group. When each group felt they had exhausted their own topic, they were encouraged to consider and add to suggestions and themes expressed on the other groups' posters.

The session was productive, with all staff contributing views. The results of this session were immediately fed back to the groups during the afternoon, at which point they were given the stakeholder interview themes for comparison. The themes and suggestions generated through these staff groups were later taken into consideration when designing the dental outreach clinical study materials.



Figure 4.3: Outreach Day Presentation



Figure 4.4: Staff Workshops

4.3.3 Methodology of Analysis

The Outreach staff workshop groups produced themes as part of the process. These were later coded as per the methods utilised on the management stakeholder interview transcripts as in Figure 4.1. The results were triangulated with results from other groups as described within section 4.1.3.

4.4 Findings from the Exploration of Existing Views on Clinical Research in Dental Outreach

4.4.1 Management Stakeholders

A total of nine interviews were carried out. The demographics of the Management Stakeholders and their previous research involvement are outlined in Tables 4.1, 4.2 and 4.3 together additional comments below:

Table 4.1 Gender and remit demographic information for management stakeholders

Demographics	Remit	Identification
3 x Female	All NHS	NHS1, NHS3, NHS4
6 x Male	2 NHS	NHS2, NHS5
	4 Academic	AC1, AC2, AC3, AC4

Table 4.2 Basic demographic information of management stakeholders

Question	Response	Number
What is your role in outreach?	Primarily Educational	5
	Primarily Managerial	4
How long have you been involved in outreach?	20 Years	1
	8 to 9 Years	3
	3 to 5 Years	5
	1 Year or Less	1

The Management Stakeholders gave examples to further explain their management roles as: handling patient complaints, financial roles or operational, such as the organisation of outreach staff.

The respondent with twenty years was an academic interviewee who was additionally involved with the very early forms of outreach delivered by Dundee Dental School in the 1990s.

Table 4.3 Involvement in research for management stakeholders

Question	Response	
Have you had previous Involvement in research?	Involvement in Clinical Research	5
	Involvement with Non- Clinical Research	2
	No previous involvement	2

All those who had had previous involvement in clinical research were positive about their research experiences while those who had been involved in development of guidelines and in non-clinical research were also positive about their involvement in aspects of research. One of the interviewees without research experience explained that they viewed research involvement only relevant to ‘career (academic) dentists’:

“I’m not a career dentist so I have no great interest in research” (NHS₅)

The interviewees welcomed the opportunity to discuss the subject of clinical research in dental outreach. However, of the two less forthcoming interviewees, (both NHS management stakeholders), one chose to avoid a number of the scheduled questions, not giving direct answers while the other seemed disinterested in the subject area. The attitude of one of these stakeholders was explained during the interview as they expressed that they:

“Didn’t see outreach as the best place for clinical research” (NHS₃)

4.4.2 Final Year Students

Four students and an outreach nurse took part in the focus group (S_b) (S_n) (S_s) (S_g) (S_f). The members of the final year group of students were asked what they perceived their role in outreach to be. The answer was unanimous: they were there to provide patient treatment (service provision).

When asked about their previous involvement in clinical research, none of the group viewed themselves as having any involvement at the level of researcher. One member had been involved as a participant and was happy with their experience. The other members were asked if they ever thought about clinical research. They again gave a unanimous ‘no’ to this question and they were encouraged to expand on this. They explained that as undergraduates they didn’t expect to have to consider clinical research themselves.

“You assume the staff are reading all the journals for you.” (S_n)

“We just go by what we’re taught.” (S_b)

Possibly, as a result of their lack of knowledge and inexperience, none of the group expressed any views on aspects of patient care which could benefit from further research.

4.4.3 Outreach Staff

A total of 37 staff attended the workshop. Four of these had previously been interviewed as part of the stakeholder interviews while the remaining 33 staff had had no previous discussions regarding clinical research in dental outreach clinics. The demographics of the staff and their previous research involvement are outlined in Tables 4.4 and 4.5.

Table 4.4: Basic demographic information for outreach staff

Question	Response	Staff Numbers
What is your role in outreach?	Dental surgery assistant	10
	Outreach supervisor	22
	Outreach management	3
	No response	2
What do you consider the main Function of your role in outreach?	Education	15
	Patient safety/support	15
	General management of the clinic	7
How long have you been involved in outreach?	More than 8 years	3
	More than 4 years but less than 8 years	5
	Over a year but less than 4	23
	Less than a year	5
	No response	1

Table 4.5: Involvement in research of Outreach Staff

Have you had the opportunity to get involved in research before?	No previous opportunity/involvement	19
	Previous opportunity or involvement	12
	Unsure	3
	No response	3
Does research influence your patient care?	Yes, often or occasionally	29
	No	7
	No response	1

4.5 Existing Views of Research in Outreach - Findings

4.5.1 Topics

The Management Stakeholders, Students and Staff were all asked to identify aspects and topics of patient care that they felt required further research and those topics

which were suitable for research in an outreach environment. A brief summary of the findings from each party are summarised below.

Management Stakeholders

Four interviewees viewed that *all* aspects of patient care required further research. Five viewed research into specific patient groups to be important - an example being the care of the elderly dental patient. Prevention, restorative care and longevity of treatment were additional topics viewed as requiring further research. One interviewee (NHS₅) was unsure of any areas which required further research, while the final interviewee (NHS₃) viewed that inequality studies and investigation into the patient experience in outreach clinics both required further research.

Research topics which were considered appropriate for the dental outreach environment by the Management Stakeholder interviewees are noted in Table 4.6.

Table 4.6: Management Stakeholder views on topics appropriate for Outreach

Topic	Number Suggesting Topic
Prevention	3
Continuity of Care	3
Patient Management	3
Longevity of Treatment	3
Outreach Clinic Issues (efficiency)	4
Treatment Planning	1
Communication	1
All Areas	1

Interviewees could suggest more than one topic and several discussed the subject at length giving several examples of areas considered suited to the dental outreach environment. One interviewee (NHS₃) viewed there to be no particular topics suitable to the outreach environment.

Final Year Students

The students, in general, had experienced minimal involvement with research and this is perhaps why they expressed limited views on research topics which they considered to be suitable for the dental outreach environment. Continuity of care was a topic discussed by the group as they considered this to be a challenge in the outreach clinics:

“....like dentures...they never seem to work...different students, different staff.” (S_n)

Caries management was also viewed as a topic they wished to have more evidence of managing in the outreach environment.

Outreach Staff

Research topics which were considered appropriate for the dental outreach environment by the Management Stakeholder interviewees are noted in Table 4.7.

Table 4.7: Staff views on topics appropriate for Outreach

Topic	Number of Topics
Treatment planning	7
Patient management	6
Prevention/self-care	6
Communication	5
Continuity issues	5
Longevity of treatment provided	3
Time taken to carry out treatment	1

4.5.2 Pre-study Perceptions of Facilitators and Barriers for Clinical Research in Dental Outreach

Each group was asked their views of facilitators and barriers for clinical research in the dental outreach environment. Views of each of the groups are outlined on the following subsections.

4.5.2.1 Perceived Facilitators to Clinical Research in Dental Outreach

Management Stakeholder Views

The people involved in the outreach clinics were viewed as being potential facilitators for clinical research in dental outreach. Thus the staff, dental students and outreach patients were all seen as potential facilitators. The staff were seen as committed to teaching and the educational environment of outreach was considered an additional facilitator. The students were seen as both enthusiastic and compliant:

‘.....used to being told what to do’ (NHS₂)

Outreach patients were viewed as being altruistic in their acceptance of receiving treatment by dental students and, additionally, their high levels of disease were seen as being of benefit to a clinical research study. The outreach clinic set-up was considered a facilitator. Clinics were viewed as modern, open plan and well equipped including a computerised patient records system which was considered to be a potential facilitator for clinical research. Although a barrier in terms of continuity, the large number of people involved in outreach was seen as beneficial in ensuring any research obtained robust and translational answers, reflective of primary care dentistry

Final Year Student Views

The student group viewed outreach patients to be the most helpful aspect of outreach clinics in relation to clinical research studies. The patients were considered specifically to be beneficial for various research topics given their high plaque and disease levels. The students also viewed the open plan nature of the clinics to be a facilitator and noted that there was often additional time available in outreach sessions which could be used for clinical research studies.

Outreach Staff Views

Outreach staff viewed themselves as potential facilitators of clinical research studies. They noted in particular: their enthusiasm, skills, flexibility and the fact that some staff already have experience of clinical studies. Postgraduate qualifications were held by many of the outreach staff were considered a facilitator. Outreach staff have access to courses and close links with the University. Many of the outreach clinics have consistency in the supervising staff which was also considered a facilitator. The students enthusiasm was viewed to be a facilitator. There was recognition of ‘down time’ during the summer months when students were not present in the outreach clinics and this was viewed as providing a period of opportunity for clinical research studies to be carried out in the clinics. Outreach patients were viewed by staff to be a compliant patient group.

The outreach staff were asked to identify solutions to their perceived challenges to clinical research in dental outreach. Outreach staff recommended the following:

- Select a suitable study which interests both outreach patients, so they sign up to it, and outreach staff;
- share staff with research experience between outreach clinics or recruit new staff if required;
- coordinate and calibrate staff to reduce inconsistencies
- Have transparent protocols to ensure continuity and provide research training for outreach staff for this;

- have protected time for staff involved in the research so they have time to carry out the research activities;
- have improved communication between staff and NHS managers to ensure NHS managers are aware of staff involvement and time the research takes, and
- collaborate with Universities over research approvals and funding.

4.5.2.2 Perceived barriers to clinical research in dental outreach

Management Stakeholder Views

The management stakeholders perceived that continuity would be a potential barrier to clinical research in dental outreach. There were different areas where continuity was considered to be a potential barrier: continuity between staff on the clinic, as outreach clinics have different staff supervising students during the course of a week; continuity between students, as there were so many dental students in the final year, keeping continuity in their delivery of a study for example when taking measures; continuity between clinics with regards to equipment and set up. Dental students were considered to be relatively inexperienced and this was perceived to be a potential barrier towards the smooth delivery of a clinical research study. The numbers of staff on the clinics were seen as a potential barrier: some management stakeholders were of the opinion that the staff on the outreach clinics were pressurised already without adding anything extra to their workload. The outreach patients were regarded to be already generous with their time and there was concern that their good-will could be lost if further demands were made on the length or number of appointments they needed to attend. The outreach patients were also viewed as having high failure to attend rates which was considered to be a barrier to arranging research reviews and it was noted that outreach patients were not regularly recalled which again could be a barrier to clinical research studies. Other noted challenges included service delivery, the amount of clinical time available in outreach, finding finance for research activities and the quality of evidence produced in dental outreach.

One of the management stakeholders did not view there to be any potential challenges.

Final Year Student Views

The students had no previous experience of clinical research, however they felt strongly that continuity would be the primary barrier to clinical research in dental outreach clinics. The open plan nature of the clinics and lack of privacy were additionally seen as potential barriers to clinical research. Continuity was viewed as the primary barrier to clinical research in dental outreach.

Outreach Staff Views

The outreach staff were of the view that the outreach patients could be a barrier to clinical research studies in outreach. Staff viewed outreach patients to have a high rate of failure to attend appointments and additionally irregular attendance patterns. The recruitment of outreach patients was considered a challenge. Staff viewed that the inexperience of the outreach clinics in clinical research could be a potential barrier, as could gaining approvals for studies in outreach. The lack of continuity between clinics was considered to be another potential challenge.

“Differences between the clinics: patient groups, geographical and staff to student ratio and nursing support”

Time factors including clinics and staff running short of time and appointments of different lengths were also noted. The enthusiasm of staff and patients especially those disinterested in research in general or in the particular topic of the study were considered a potential barrier.

4.5.3 Advantages and Disadvantages of Clinical Research in Dental Outreach

The management stakeholders, outreach staff and students were each asked about their views on potential advantages and disadvantages of clinical research in dental outreach with respect to:

- the staff who work on outreach,
- the students who deliver the dental care in outreach,
- the patients who attend outreach clinics, and
- the Dental Service (SDS).

4.5.3.1 Advantages and Disadvantages for Staff

Management Stakeholder Views

The advantages for dental outreach staff delivering clinical research in dental outreach were seen as: The provision of an increase in opportunities for continuing professional development for outreach staff, and the increase in staff knowledge and skills as a result of research training. The increase in the variety of work of the staff was considered to have the ability to increase the interest and enthusiasm of outreach staff in their role. Additionally, the interviewees viewed that carrying out research might encourage clinicians to consider their own practice and their own patient care.

In terms of disadvantages, five of the interviewees were of the view that the outreach staffs' concept of service provision would be the greatest disadvantage, by this they referred to the delivery of patient care. This concept of service delivery in terms of patient care was further defined as the number of patients seen on outreach, the number of completed treatment plans and the time taken to complete patient treatment:

“The pressure on the people who are supporting outreach, it’s not just around teaching, it’s around service delivery as well.”

(NHS₄)

Other views of disadvantages for staff included:

The potential to demotivate outreach staff if they were not interested in carrying out clinical research; and keeping the interest of staff during their involvement in studies in outreach. Management stakeholders viewed that research training and clinical research delivery would take up staff’s valuable clinical time. Staff were also of the view that as a group they may feel that clinical research was distracting from the “*real*” focus of outreach, which they considered to be:

- providing primary care dental treatment for patients and,
- experience of general practice for the students

A further perceived disadvantage for outreach staff was the idea that the skills of staff may not be fully utilised in delivering clinical research and that outreach staff may feel deskilled as a result. Funding was also mentioned as a possible disadvantage, although this was not further elaborated on as to how it would be a disadvantage to staff.

One interviewee considered that there would be no disadvantages for their staff in delivering clinical research in dental outreach.

Final Year Student Views

Advantages for staff delivering clinical research in dental outreach were seen as a Curriculum Vitae (CV)/career enhancement, improved variety of work and the benefits from delivering evidence-based healthcare.

In terms of disadvantages, the student group were of the opinion that staff in outreach might feel pressurised by clinical research activities:

“If they were trying to look after the clinic as well as doing research... it may be a bit too much to handle.” (S_g)

Outreach Staff Views

The outreach staff workshop groups identified what they considered to be the advantages of clinical research in dental outreach. They considered the links that were already in place with the University of Dundee could be further strengthened through the delivery of clinical research in outreach and that this may in time lead to improvements in support for student assessment and in ensuring maintenance of teaching standards. They were of the opinion that there could be an improvement in staff education through the delivery of research and that there would be cultivation of an interest in clinical research within the Salaried Dental Service. They were of the overall view that this could lead to an improvement in the quality of clinical dentistry delivered and improved patient satisfaction. It was also noted that there may be a possibility of publications arising from clinical research in the outreach clinics.

In terms of disadvantages, staff were of the opinion that the delivery of clinical research would put increased demands on staff time and that management may not understand implications of any research activities impacting on staff time. The extra activities associated with the delivery of clinical research were considered to have the potential to increase staff stress. Staff were of the opinion that their clinics were already understaffed and busy and that this could potentially cause patient safety issues if staff became tied up in research activities and could not give the clinical dentistry their full attention. Overall clinical research was seen to be a potential burden for the staff. The topic of research may not be of interest to some staff; there would be training required which would take up time; there may be issues with consent and ethics approvals; there could be funding issues and that clinical research could place an extra burden on the students. Staff were of the opinion that students

should be spending their time carrying out clinical dentistry and clinical research was not considered part of this.

4.5.3.2 Advantages and Disadvantages for Students

Management Stakeholder Views

There were a greater number of considered advantages for dental students than disadvantages. The interviewees on the whole were of the view that carrying out clinical research in dental outreach could lead to the realisation that research may be carried out in general dental practice. It was viewed that dental students could potentially gain an understanding of research and an increased awareness for the requirement to provide evidence based care.

“I don’t think they have the faintest idea what it actually means...and I think it would be useful to understand that it actually does have an impact on real people and on them as clinicians” (NHS₄)

It was also viewed that, for some students, carrying out clinical research in dental outreach may help with career development arising from experience within a different field with the potential to create a positive view of clinical research, thus increasing their desire for learning.

In terms of disadvantages, the management stakeholders were of the view that carrying out clinical research in dental outreach could potentially decrease clinical experience for dental students. They were also of the view that students might not be interested in clinical research and that some students may find it confusing when outreach was already such a new environment for them.

Final Year Student Views

The students also cited enhancement of CVs as a potential advantage to themselves alongside the opportunity increase their understanding of clinical research:

“It would maybe help you understand the papers better!” (S_n)

“Make research more accessible.” (S_g)

“Compare it to first year anatomy: you get the lectures but when you actually go in and dissect it yourself it definitely sticks in a lot more.” (S_g)

The majority of the group were of the opinion that there was usually plenty of time in outreach and that they would rather be doing something productive than have an empty chair. Any activity was considered preferable to no activity.

In terms of disadvantages, the students were also of the view that research in outreach might be confusing for dental students. The student group discussed the use of the outreach clinics for gaining appropriate clinical experience. A minority of the group were of the opinion that a study involving oral hygiene instruction would not be the best use of their clinical time, which they felt should be spent carrying out more complicated dental procedures during their final year, and could reduce their educational experience.

Outreach Staff Views

Potential advantages for students carrying out clinical research in dental outreach were identified as providing the opportunity for dental students to develop a positive mind-set towards clinical research and develop an understanding that research can be undertaken in primary care. This was viewed as allowing students to learn more about how research works and add this experience to their CVs, with the added possibility of getting involved in publications helping their future employment

opportunities. This was considered to be sustainable for future years if the project rolled down the years. Carrying out clinical research was considered to have the advantage of identifying effective treatments and possibly going on to build an evidence-based database to inform the teaching of future years of students.

Potential disadvantages for dental students carrying out clinical research in outreach were identified by staff as: a distraction from ‘clinical’ dentistry procedures, an additional stress for students as they would have more to think about and the disadvantage of the inability to see a project through to completion given the timescales involved in clinical research.

4.5.3.3 Advantages and Disadvantages for Patients

Management Stakeholder Views

The Management Stakeholder interviewees’ viewed potential advantages for outreach patients as having an improvement in patient care, potentially for individuals participating and as a result in finding out what treatments are effective. They were of the view that the increase in enthusiasm generated by clinical research studies in outreach could be advantageous for patients as there would be more of a ‘vibe’ about the clinic and patients would benefit from the renewed enthusiasm of outreach staff. It was also viewed that the patients would enjoy the feeling of being able to give something back to the clinic:

“It would make them feel valued and make them realise that they have some kind of influence over their own health, and perhaps the health of others.” (AC₂)

In terms of disadvantages, management stakeholders were of the view that clinical research may result in an increase in the number of failed appointments as outreach patients may drop out of treatment if they perceived it was taking too many appointments or too long.

Seven of the Management Stakeholder interviewees were of the view that participating in clinical research would potentially take up more of the outreach patients' time. There was a viewpoint that patients would not be interested in clinical research activities as they "*just want work done*" and that some patients would view it as "*too much of a fuss*" (NHS₂). Three of the Stakeholder interviewees viewed there to be no disadvantages to outreach patients.

Final Year Student Views

The group did not think that outreach patients would be disadvantaged by research in outreach. The outreach patient group were seen as grateful for treatment and generally helpful due to the fact they don't pay for the treatment they receive. This relationship was seen as advantageous for clinical research. Students were then asked directly about patient time. The group came to the opinion that, although outreach patients may have to spend a little extra time in the dental chair in order to participate in clinical research activities, this in fact would be advantageous to them as patients. In the student opinion, participants in the clinical research study would be receiving extra time for their treatment, and this would be ultimately beneficial. The students were of the view that any research which would be disadvantageous to participants would not be granted ethics approval. The group then went on to discuss the relationship they felt patients had with the clinic, focusing on the point that treatment delivered within outreach is free from financial payment. They were of the opinion that the lack of financial payment was likely to result in patients being happier about participating in clinical research, especially if the topic would be part of their required treatment. The student group perceived advantages for patients, in relation to participating in oral hygiene studies during outreach appointments, to be: increased knowledge of preventive oral care, a free toothbrush and having a little more time spent on their overall care.

Outreach Staff Views

Outreach staff agreed with the management stakeholders that clinical research in dental outreach clinics could potentially improve patient care and the motivation of staff on outreach clinics. They were of the view that clinical research may improve the continuity in teaching between the outreach clinics. Additionally they identified that there could potentially be financial payments to participants during clinical research studies.

Disadvantages of clinical research for outreach patients as identified by outreach staff were: that there could be less availability of appointments for outreach patients if research studies were taking up chair time. Outreach patients might be required to attend extra appointments for clinical research and thus could result in additional expenses for travel as well as extra time off work and that this could increase the failure to attend rates further reducing the availability of appointments. It was considered that clinical research procedures would take up more time - for example consent forms would need to be signed. Outreach patients could feel disadvantaged if staff spent less time with each patient due to the increased pressure on outreach staff.

4.5.3.4 Advantages and Disadvantages for the Service

Management Stakeholder Views

When asked about viewed advantages of clinical research in dental outreach for the dental service, eight of the Management Stakeholder interviewees were positive in their responses. Management stakeholders were of the view that there could be long term advantages related to finding out which treatments were effective and that this information could go forward to inform policies at both local and national level.

“Directing efforts towards things which work!” (AC₃)

The progression of the service through research was seen as positive and was viewed as having the potential to encourage a positive atmosphere for the service. When asked to consider the advantages to the service of clinical research in outreach, only one interviewee expressed negativity:

“Doubt the service would care!”(NHS₅)

In terms of disadvantages, there was a strong view that the main disadvantage would be the potential for clinical research to result in a reduced throughput of patients receiving treatment (eight of the nine Management Stakeholder interviewees). Two Management Stakeholder interviewees considered that there would be no potential disadvantages for service.

Final Year Student views

The students expressed few opinions about the impact that clinical research in outreach could have on the dental service. They were however of the opinion that increased research activities would result in kudos for the clinics and that this would be advantageous to outreach clinics. More effective dental treatments, established from clinical research evidence, were considered to have the ability to save money for the service in the longer term.

“If you’re giving oral hygiene instruction to every patient, surely you’re going to save yourself some fillings somewhere along the line....so you can save money.” (S_n)

4.6 Oral Hygiene as a Topic for Research in Outreach: Findings

The Management Stakeholders and the Students were asked their views on whether they considered Oral Hygiene Instruction as a suitable topic for a study and in particular if this topic was suited to Outreach Clinics. Their views are summarised below:

4.6.1 Management Stakeholder's Views

Six Management Stakeholders agreed that oral hygiene instruction would be a good topic of choice for clinical research studies in dental outreach clinics. Two Management Stakeholders had no particular view on the topic and the remaining stakeholder declined to answer the question. Management Stakeholders were of the view that students were in fact good at delivering oral hygiene instruction and were interested in the topic. However some of the Management stakeholders interviewed were of the opinion that final year dental students may see this as compromising their experience during their last year; that oral hygiene instruction was in fact a topic which would better suit less experienced dental students. For this reason it was felt that the students might require some motivation in order to complete the study. The patient base was seen as in need of oral hygiene instruction but largely unmotivated.

'They (outreach patients) are a hard group to reach!' (NHS₄).

The topic of oral hygiene was viewed as being most fundamental to patient care, additionally relevant and applicable to all patients and was, in general terms, currently perceived to be undervalued by outreach patients. Measures for oral hygiene as a clinical study area were viewed to be straightforward and overall it was considered to be a good choice of topic for outreach.

4.6.2 Final Year Students' Views

The group were unanimous in agreement that it was a good topic. They elaborated:

"Patients don't feel it is an important part of the treatment plan." (S_s)

The group additionally discussed that they viewed oral hygiene instruction to be a personal topic and that the relationship with patients had with the outreach clinic was viewed to be fragile. Although considered as a good topic choice, oral hygiene

instruction delivery was additionally viewed as an awkward area to broach with patients:

“I feel awkward doing it as these people (outreach patients) feel a wee bit ashamed.”
(S_s)

The Students’ felt that their young age made the topic difficult to deliver:

*“When you are like sixty-three and you’ve got this twenty-one year old saying
‘you’re not brushing your teeth properly’”* (S_g)

They were of the view that delivering oral hygiene as a clinical research study would make it an easier subject to broach with their patients:

“It would feel much less patronising: ‘Oh, it’s just research!’” (S_n)

The group was of the view that oral hygiene instruction would be a good choice of topic, as it was considered to be part of their usual patient care on the outreach clinics. However, they also viewed oral hygiene as overlooked, in the pressure to provide ‘treatment’ for their patients. They viewed the relationship the patients have with the clinic to be fragile and that they were concerned that the provision of oral hygiene instruction was not perceived to be of value by the patients, and that this may put patients off returning for treatment.

*“All (the patients) want is a new denture, to replace the broken one...and sometimes
you get the feeling they aren’t all that bothered about (prevention)”* (S_n)

One student, however, disagreed strongly with the view that there was pressure from patients to provide particular items of dental treatment. This particular student wasn’t aware of any pressure from patients to not provide preventive care. She joked:

“Maybe my patients are scared of me so they don’t say!” (S_s)

At this point the opportunity to investigate the students’ perception of the relationship the patients had with the clinic arose. The view which had emerged from the management interviews was that the clinics were “*indebted*” to the patients (NHS₁) for attending. Management Stakeholders held the view that the patients thought they were in fact ‘helping’ the students by attending for their dental appointments. When this idea was put to the student group it was strongly refuted:

“I think a lot of them are just glad they are getting treated!” (S_t)

“You’re doing it (the treatment) for free; and you’re doing a good job!” (S_s)

4.7 Advantages and Disadvantages of Oral Hygiene Research in Outreach

Barriers and facilitators to research in outreach clinics in general had been considered earlier and are noted elsewhere however, in summary, the prime issues raised included:

- The high number of failed appointments in outreach
- Continuity, given the number of people involved
- Keeping the message consistent
- The view that the outreach patient group was largely unmotivated

Management Stakeholder and Final Year Student groups were also asked to identify what they saw as advantages and disadvantages specific to an oral hygiene clinical study in outreach clinics.

Management Stakeholders

Six of the Management Stakeholders interviewed viewed the topic of oral hygiene to be fundamental to all treatments delivered in the outreach clinics and that research in

this environment of this topic had the potential to reduce disease through prevention. Management stakeholders were of the view that research around the topic of prevention would be beneficial for outreach patients and in particular, two Management Stakeholder interviewees viewed that patients would be able to immediately see the benefit of such research and a further two perceived social advantages for participants in the study (by improving their oral hygiene). The encouragement of clinicians auditing their own work was considered to be a further advantage.

It was viewed by all Management Stakeholders that, as oral hygiene instruction was a standard form of prevention delivered in the clinics, this would be an advantage for oral hygiene research studies and it was noted that the outreach clinics already have links to similar projects based on prevention such as Childsmile™.

One NHS Management Stakeholder interviewee did not think there would be any particular advantages of oral hygiene based studies, while the question was refused by the remaining NHS Management Stakeholder (NHS₅).

The greatest perceived disadvantage from the Management Stakeholder interviewees in relation to oral hygiene as a research topic was continuity. The managers identified that there could be difficulty in maintaining continuity in technique when recording plaque and bleeding measurements. Further continuity challenges included keeping the message the same between student and the ability of the student to modify the oral hygiene techniques based on patient's circumstances. The continuity between staff on the clinics was viewed to be a potential challenge and changing staff rotas were viewed as a threat to staff engagement with a clinical study. Continuity between outreach clinics in terms of the difference in outreach patient demographics between clinics was also identified as a potential challenge.

Related to continuity was the relationship outreach patients have with the outreach clinics. There was a perception that as outreach patients often attend the clinics for a single course of treatment rather than longer term preventive care, thus outreach patients were perceived to have a different relationship with the clinics than would

be present in general practice dentistry. The difficulty in building trust with this patient-clinician relationship when the clinician (student) changes often was seen as a barrier especially in relation to studies into oral hygiene instruction, which was regarded as a personal subject requiring rapport.

Disinterest from the outreach patients was viewed as a challenge as the patients who attend outreach clinics were not perceived to be as interested in oral health as the cohort of patients attending general dental practice. There was also a view that final year students may be disinterested in the topic and fail to engage with the study.

The lack of designated oral hygiene sinks within outreach was viewed by two NHS Management Stakeholders to be a potential issue. Two of the Management Stakeholders did not view there to be any particular problems with oral hygiene based studies in the outreach setting.

Final Year Students

Students viewed a focus on prevention to be important as having the potential to reduce dental disease. They additionally held the view that it would:

“.....provide a less embarrassing way to deliver oral hygiene instruction,” (S_n)

and encourage students to,

“.....get into the routine of just getting on with it!” (S_g)

The only particular disadvantage of oral hygiene studies in outreach viewed by the students echoed comments made by Management Stakeholders: - the lack of dedicated oral hygiene sinks in the clinics.

The majority response of the group to the prospect of clinical research in dental outreach clinics was positive. Only one member came across as indifferent during some of the discussion points.

4.8 Triangulation of themes identified in Pre-Study interviews, Focus Groups and Workshops

Following completion of the pre-study qualitative work with the Outreach Management Stakeholders, final year students and staff, the emerging themes identified in relation to clinical research in dental outreach are triangulated below:

4.8.1 Time

- Student Time – this was seen as a positive in relation to clinical research in outreach by all three groups as students were considered to have time to carry out clinical research.
- Staff Time – this was seen as scarce and both staff and student groups were of the opinion that outreach staff were already pressurised and clinical research could be another contributing factor to this pressure. Staff groups considered this could be assisted by the allocation of outreach staff time by outreach managers in order to carry out clinical research activities.
- Patient Time – although this was seen as plentiful by the final year students, staff and management stakeholders were concerned that outreach patients may not wish to give up further time for research in outreach on top of the time spent monitoring their oral dental care.

4.8.2 Continuity

- Of Student and Patient – this was seen as a barrier by all three groups however students viewed this as advantageous towards oral hygiene instruction delivery.
- Of Teaching Staff – rotation of staff between different clinics was seen as a potential challenge to clinical research in outreach.
- Of Teaching Method – this was seen to be a challenge in terms of keeping the oral hygiene message the same between clinics and patients.

- Of General Teaching in Outreach – the possibility of improving the continuity of outreach teaching through research, which was viewed as a positive.

4.8.3 Relationship

The relationship the patients have with the outreach clinics is seen as fragile by the management stakeholders and the outreach staff. The students however, although recognising that the relationship could be viewed as fragile, were of the opinion that as the patients were receiving treatment without financial payment, that the relationship would not likely be affected by clinical research activities, particularly if it were part of the usual treatment of the patient would be receiving in outreach.

4.8.4 Outreach Service Delivery

The throughput of patients was a concern to both management stakeholders and outreach staff. Dental students noted their primary role in outreach to be service delivery. They were however of the view that this would not be affected by clinical research in dental outreach. This differed from the views of the outreach staff and management stakeholders who both viewed that clinical research as a potential threat to service delivery in outreach clinics.

It was noted that whether or not service delivery in outreach would be considered threatened by clinical research activities was dependent on the way service delivery was measured and whether clinical research was considered to be part of the normal service delivery. This was also the view of the students. The staff however, viewed service delivery to relate only to completed treatment items and treatment plans. The staff viewed that clinical research could impact on this type of service delivery.

4.8.5 Education

All three groups viewed that there would likely be educational benefits of carrying out clinical research in dental outreach both for outreach staff and for the final year dental students.

The value of the service learning more about whether clinical research could be carried out was additionally noted by both management stakeholders and outreach staff.

All three groups were of the view that clinical research in dental outreach could increase dental students' knowledge of clinical research. All three groups noted that there would be the probability of improving outreach staff development and giving better future job prospects and that clinical research would be educational for outreach staff. The ability to build new skills and improve CV strength was noted as important by all three groups.

4.9 Exploration of Existing Views on Clinical Research in Dental Research – Discussion

The pre-study exploration met the objectives of exploring the views of i) Management Stakeholders, Final Year Dental Students and Outreach staff on the topic of carrying out clinical research in dental outreach, ii) the potential barriers and facilitators to clinical research in dental outreach and iii) the potential advantages and disadvantages of clinical research to the groups involved. These views were validated through the concurrence of the main themes and findings.

All three groups were supportive of clinical research in dental outreach. The outreach staff were slightly more reserved in their enthusiasm when compared to that of the Management Stakeholders and the Final Year Dental Students. This was most likely to be due to concerns of the outreach staff regarding the level of extra work involved with clinical research and the potential lack of time available for staff to carry out said work within the clinic timeframes available.

The topic of oral hygiene instruction for clinical research in outreach was supported by all three groups. However, the Final Year Student group had a more mixed response to the subject. Some of the group thought the topic was important, manageable, and relevant to outreach patients, there were muted concerns from others in the group that the topic could potentially be of no interest to Final Year Dental Students. This view was also echoed by Outreach Staff and Management Stakeholders.

The outreach clinics were considered ideal facilities for clinical research by all three groups. The outreach patients themselves were considered an important resource for clinical research. The commitment of the outreach staff and the set-up of the clinics were additionally seen as beneficial in facilitating clinical research.

Outreach patients were seen as a potential barrier to clinical research in dental outreach by all three groups, due to their high rate of failure to attend appointments. This was considered to have the potential to negatively impact on any clinical research study in dental outreach.

The dental students were seen as beneficial for clinical research in dental outreach especially as they were considered by the outreach Management Stakeholders to be already proficient at oral hygiene instruction delivery. However clearly worded protocols were considered to be of primary importance.

There were considered to be potential advantages for all groups involved and relatively few disadvantages identified. The summary table of identified advantages and disadvantages for the groups involved, as shown in Table 4.8.

The groups were of the collective opinion that if a clinical research study did not take up too much clinical time and that the clinics were well supported during any research process, that there would be relatively few disadvantages. It was recognised that outreach patients could potentially be disadvantaged in terms of their time. However, as any clinical study would have to undergo ethical approval, this was considered likely to be minimal.

There was recognition that students who were not interested in clinical research or the study topic could feel disadvantaged by the clinical research. However, the generally accepted opinion was that there are other aspects of the dental curriculum that this could easily apply to and that the students would overall be advantaged by gaining the extra experience of clinical research.

It was suggested that dental outreach nurses be involved in clinical research studies to reduce the concern that they could feel disadvantaged if their skills were not utilised by research activities. This would have the potential advantage of building new skills for the dental outreach nurses.

Table 4.8: Identified advantages and disadvantages of clinical research in dental outreach to the groups involved

Group	Advantages	Disadvantages
Final Year Dental Students	Experience of clinical research Strengthening of CVs Use up additional clinical time in outreach	May not be interested in research May not be interested in the topic
Outreach staff	Experience of clinical research Ability to fully utilise skills Strengthening of CV Increase future career prospects Increase job satisfaction	Further addition to workload Staff already at limits of what can be delivered- extra stress May not be interested in clinical research
Outreach Patients	Like to be involved in teaching, may enjoy research Input into future treatment improvements May get more attentive treatment Opportunity to get involved in research	Staff may be more stressed on the clinic May take extra time/appointments
Dental Service	Moving service forward Informing policies Treatment proven effective	May lose patients May have less completed treatment plans Could have increase in failure to attend appointments

Chapter 5 – Choice of Clinical Research Study for the Dental Outreach Environment

5.1 Choice of Clinical Research Study for the Dental Outreach Environment

It was anticipated that dental outreach clinics would be a good place to conduct clinical dental research (Section 1.3). Exploratory interviews (Chapter 4) with outreach management, staff workshops and the student focus group had concluded that the dental outreach clinics had a number of factors which would facilitate clinical research studies (Section 4.8). Exploratory work had asked the various groups involved in dental outreach clinics about their views of suitable topics for clinical research within a dental outreach environment.

This was the first clinical study conducted at dental outreach clinics in Scotland and thus, with a view to minimising challenges, it was desirable that the study fulfilled the following criteria:

- quick and safe to deliver and causing minimal disruption to scheduled appointments,
- the intervention should be low risk,
- measurements should be straightforward and part of a normal patient examination,
- expensive equipment should not be required,
- potential to involve large number of outreach patients,
- the outcomes should be measureable (plaque and gingival margin bleeding scores), and
- the effects of the intervention should be suitable for follow up within one academic year.

5.1.1 An Oral Hygiene Study

Addressing the high levels of preventable dental disease in outreach was deemed to be desirable and therefore a clinical study centred around the topic of prevention of caries and periodontal disease had the potential to involve all dental outreach patients with natural teeth. The most common form of preventive care carried out in the dental outreach clinics was oral hygiene instruction (Watt 2010). The delivery of oral hygiene instruction had been considered a suitable topic by the groups which were consulted during the exploration stage (Chapter 4). In addition, the delivery of oral hygiene instruction is considered an essential part of dental care in the relation to preventing future disease. Students frequently provide oral hygiene instruction to outreach patients, many of whom have not received preventive advice previously. For patients with periodontal disease or caries, oral hygiene instruction is considered a fundamental component of their treatment plan. At the time of the study, the GDC interim guidelines for dental schools (GDC 2008) highlighted the importance of teaching a preventive approach to dentistry: new graduates should be competent to carry out ‘...oral hygiene instruction, dietary analysis, topical fluoride and fissure sealants’. The topic of oral hygiene instruction was considered to be relevant to dental undergraduates, their outreach patients and the primary care service.

In addition to its relevance to the groups involved in outreach, oral hygiene instruction fulfilled Scottish Government research strategies, as outlined in the Research Strategy for Health and Healthcare (Scottish Government 2009): prevention of disease and increase of home care; encouraging patients to take responsibility and control of their own health. This further strengthened the topic as a worthwhile choice. Oral hygiene instruction therefore fulfilled all of the desirable criteria, fitted well within the GDC interim guidelines, was relevant to all groups and was therefore chosen as the topic for the outreach clinical study.

Observational studies carried out by the author over a two-week period in the outreach clinics and also in the final year clinics within Dundee Dental School confirmed that there was no particular preferred method of oral hygiene instruction

delivery by final year students within the clinics and that the students varied in their approach.

5.1.2 One-to-One Oral Hygiene Instruction in the Dental Setting

The primary aim of this thesis was to determine the feasibility of conducting clinical trials in dental outreach clinics. The area of research suitable for a clinical trial in outreach had been decided however the protocol to undertake this trial should replicate a previously conducted and relevant clinical study. To inform the study design, a literature search was carried out to identify relevant clinical studies in the field of oral hygiene instruction delivery. Two primary sources of information were consulted to identify current literature reviews within the field: The Cochrane Library and Scopus. The Cochrane Library revealed one completed review of oral hygiene instruction delivery (Renz et al. 2008), and one review at the protocol stage (Soldani 2008). Scopus identified one recent additional relevant review by Chapple (Chapple 2009).

The systematic review by Renz entitled ‘Psychological interventions to improve adherence to oral hygiene instruction in patients with periodontal disease’ (Renz et al. 2008) identified four studies which met with their inclusion criteria. Unfortunately, due to the time-intensive deliveries involved none of these interventions were considered directly transferrable to primary dental care.

The Cochrane literature search carried out by Soldani’s group, on ‘One-to-one oral hygiene advice provided in a dental setting for oral health’ had identified 120 papers eligible for risk of bias assessment. As our study was to investigate the suitability of the dental outreach environment to support clinical research, replicating a research model which was already tested for the primary care dental environment was desirable.

The authors of Soldani’s Cochrane review gave their permission for the final 120 papers which were to be assessed for risk of bias to additionally be assessed for suitability for replication in the dental outreach clinics. The papers were consulted,

with the aim of identifying an appropriate methodology transferable to dental outreach clinics.

The papers were assessed for the following inclusion criteria and, in parentheses, the relevance to this PhD:

- a randomised controlled clinical study (high quality methodology),
- carried out in primary care setting (outreach clinics are a primary care setting),
- carried out by multiple practitioners (there were 65 dental students in the final year, all with the potential to recruit participants),
- carried out in multiple clinics (there were six outreach clinics which would be involved in the study),
- involving a low risk intervention (considered appropriate for final year dental students to deliver in terms of skill),
- intervention which was quick to deliver (ideally fitting into the allocated outreach appointments), and
- an intervention which was inexpensive (there were limited funds available for this first study in outreach).

5.1.3 Identifying a Suitable Study

During consultation of papers, one particularly suitable study was identified as ‘Influencing patient oral hygiene behaviour effectively’ (Clarkson et al. 2009). This study had delivered oral hygiene instruction in a primary care setting and had involved vocational trainee dentists. The vocational trainee dentists were of similar age and experience to the final year dental students at Dundee University. The study by Clarkson (Clarkson et al. 2009) was conducted in primary care and involved multiple practices and practitioners. The topic and methodology together with the age and number of dentists involved in the study made it a suitable choice of protocol to be replicated in the outreach clinics.

The Cochrane review by Renz (Renz 2008) had demonstrated that a psychological approach to behaviour change was of benefit to dental patients. The approaches included in this review were however considered too labour intensive for primary care dentistry. With this in mind and focussing on suitability for primary care dentistry, Clarkson's group had developed a five minute oral hygiene instruction intervention (Clarkson et al. 2009). Their psychologically framed, evidence based approach to delivery of oral hygiene instruction, proved to be effective in reducing plaque and bleeding over an eight week period in primary care dental patients, when compared with a control group.

The Clarkson (Clarkson et al. 2009) study was delivered in two legs. The results of each leg had been analysed separately and compared. The first leg of their study was delivered as a randomised and controlled clinical study in which the participants were randomly allocated to either a control or an interventional oral hygiene instruction delivery group. The second leg of the study was delivered as a cluster randomised and controlled clinical study. In this second leg, the dentists were randomised into two groups to deliver either control or interventional oral hygiene instruction to their patients. By comparing the data from the two legs of their study, Clarkson's group examined the possible contamination of the method of delivery within each group: the patient randomised oral hygiene instruction (OHI) where practitioners delivered both forms of advice and the cluster study where practitioners delivered only one form of advice. They found no significant evidence of contamination of the control group with the interventional delivery when the dental practitioner delivered both forms of OHI. This was helpful in the light of the proposed study since some of the outreach clinics were open environments which allowed the students to view each other delivering interventions, and in other clinics students often worked in pairs. The findings of the vocational dental practitioner study (Clarkson et al. 2009) provided the necessary information to enable the author to select a cluster randomised controlled study design for ease of group allocation. This design also provided reassurance that students could deliver interventions cleanly.

The review ‘Periodontal Treatment: Where does the future lie?’ (Chapple 2009), provided additional evidence in support of the use of a psychological approach to behaviour change within current approaches to prevention. Chapple’s paper discussed the potential for use of biomarkers in dentistry. A biomarker is an indicator of disease that patients with the disease can recognise. The integration of biomarkers has been successfully utilised to strengthen adherence to preventive behaviours in other health care areas such as diabetes and smoking cessation (Vermeire et al. 2001) (Barnfather et al. 2005). The first sign of gingival disease has a very clear biomarker, that of gingival bleeding (Lang & Lindhe 2009). Patients are often aware that their gums bleed, but may not be aware of the significance of this or know how to address this bleeding (Croxon 1998). Gingival bleeding as a biomarker was used successfully in one, albeit small, trial identified by the Soldani’s Cochrane literature search which evaluated interproximal cleaning (Walsh et al. 1985). Walsh et al. found the indicator of gingival bleeding to be successful in motivating home care compliance thereby improving the gingival health of their participants.

Clarkson’s study had seen 50, in a cluster RCT, and 37 in a patient RCT, Vocational Trainee dentists recruit participants to the study. These intervention participants received a power toothbrush and instruction on how to use it which was framed using the a psychological theories of Bandura and Gollwitzer (Bandura. 1998; Gollwitzer. 1999). Clarkson measured reported behavioural change in the participants as a primary outcome. The cognitive measures of self efficacy and intention were additionally measured. A further secondary measure was plaque and gingival margin bleeding of participants which was measured using Loe and Silness index. Clarkson’s dentists recruited a total of 778 participants and measured 281 at the 8 week follow up visit.

In summary, the protocol outlined by Clarkson (Clarkson et al. 2009) - a randomised control cluster trial - would be utilised, with the additional biomarker of gingival bleeding incorporated into the interventional oral hygiene instruction. The study was titled “The Dental Outreach Oral Hygiene Study” (DOOHS).

5.1.4 Objectives of the Dental Outreach Oral Hygiene Study

The primary objective of the Dental Outreach Oral Hygiene Study (DOOHS) was to conduct a clinical research study within dental outreach clinics and to use this study to test the practicalities of delivering clinical research in a dental outreach environment (Chapter 3).

The Dental Outreach Oral Hygiene Study had two further objectives:

1. To assess the effectiveness of oral hygiene instruction delivery on the periodontal health of dental outreach patients in the short term (3 months) and long term (6 months). Periodontal health was taken as lack of gingival bleeding on probing.
2. To assess change in reported oral hygiene behaviours after each method of oral hygiene delivery of dental outreach patients in the short term (3 months) and long term (6 months).

These objectives tested the following null hypotheses:

1. **H₀** Delivery of oral hygiene instruction using a psychological framework with the inclusion of biomarker information results in no added improvement to gingival bleeding when compared to standard oral hygiene instruction delivered within outreach clinics in the short (3 months) or long term (6 months).
2. **H₀** Delivery of oral hygiene instruction using a psychological framework with the inclusion of biomarker information results in no added increase in reported oral hygiene behaviours, when compared to the standard oral hygiene instruction delivered within outreach clinics in the short (3 months) or long term (6 months).

5.2 Development of Dental Outreach Oral Hygiene Study (DOOHS)

The protocol (Appendix 5) for DOOHS was developed in collaboration with the Tayside Academic Health Science Centre (TAHSC) and the Scottish Dental Practice Based Research Network (SDPBRN).

5.2.1 General Study Design

This study was designed and delivered as a randomised controlled cluster trial. The students were randomised. This was easy to carry out using SPSS and this eliminated the requirement for participant randomisation. Telephone randomisation of participants was considered difficult in the outreach clinics, which were already identified as being hectic environments by the pre-study work (Chapter 4). Randomisation of dental students reduced any potential confusion as to which intervention method was to be employed. The final year students were therefore randomised using SPSS software and allocated into two groups, delivering either interventional or control oral hygiene instruction.

5.2.2 DOOHS Eligibility

Dental students were tasked with recruiting participants, and were therefore responsible for screening outreach patients for eligibility and ensuring that inclusion criteria were met. These criteria were included in the Case Report Form (CRF) for reference (Appendix 9). The CRF required the student to check off a list of eligibility criteria before consenting a patient for the study.

The criteria for exclusion were:

- Patients without any natural teeth
- Patients with a medical history contraindicating probing of the gingivae (e.g. known bleeding disorder)

- Patients aged 16 years or under
- Pregnancy
- Patients with no gingival bleeding, or plaque at baseline (therefore not requiring oral hygiene instruction as part of their treatment)

5.2.3 Consent

The issue of consenting participants for a clinical study in outreach was discussed with the Tayside Academic Health Science Centre (TAHSC). TAHSC provides advice to University of Dundee researchers on clinical trials. They considered the issue of dental students consenting participants for clinical studies in comparison with consenting patients for irreversible dental procedures normally carried out on undergraduate clinics. This was the first time TAHSC had advised on the matter of undergraduates carrying out the role of clinical researcher. It was agreed that, as students are not registered with a professional body, they could not take sole responsibility for consenting participants to take part in a clinical study. Therefore, consent for the Dental Outreach Oral Hygiene Study would be undertaken jointly between a General Dental Council (GDC) registered member of dental staff on the clinic who was also Good Clinical Practice (GCP) trained and the treating dental student. The process of consent was therefore overseen by GCP trained outreach staff including dental nurses and outreach supervisors. The consent form, which was completed in triplicate, subsequently was retained by:

- the participant,
- the outreach clinic, and
- the research team.

This method of consent taking was confirmed as acceptable by the Fife and Forth Valley Research Ethics committee. A copy of the confirmation letter is included within Appendix 6.

5.2.4 Allocation of Study Identification Numbers

In order to be randomised into control and intervention groups the students had been randomly allocated specific researcher numbers using SPSS software. Their numbers were, in turn utilised to provide each study participant with their own study identification number. The methodology for creating the ID was as follows:

- the two digit student number provided the first two digits,
- the outreach clinic number (01-06) provided the second two digits, and
- the participant number that the consenting student recruited provided the final two digits.

This ensured each participant had a unique identification number which was simple to allocate at chair side.

Figure 5.1 shows an example of student 23, attending Springfield outreach clinic (site 01), recruiting their second participant (02) and therefore issuing ID number 23 01 02 to the study participant.

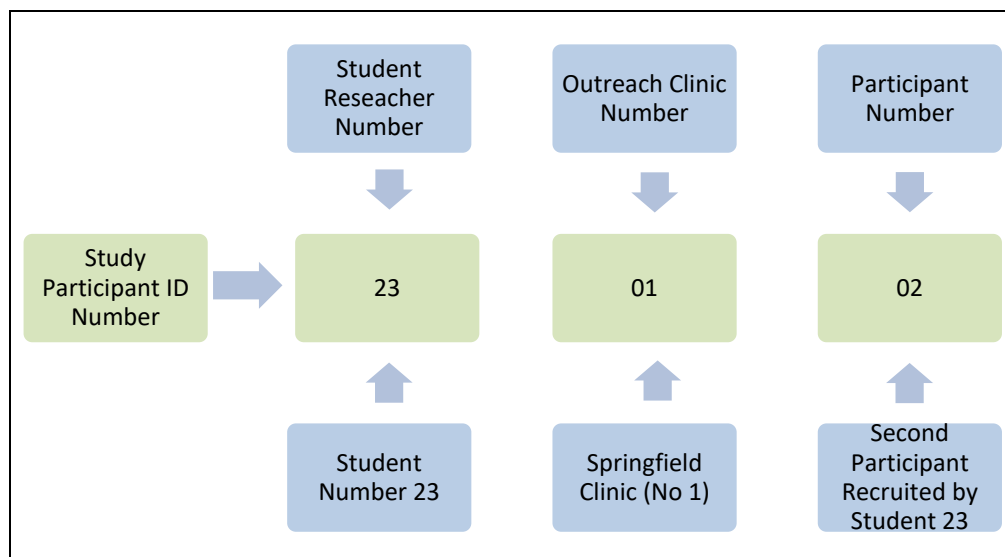


Figure 5.1: Schematic diagram detailing the method of allocation of study identification codes for participants of DOOHS

Participant identification numbers (ID) were recorded on the site recruitment log sheet in order that participants could be later identified and matched to their addresses. The study ID numbers were used to track the participants' questionnaires and charts throughout the CRF. It was the responsibility of the students to ensure the participant ID was recorded onto the CRF, the questionnaires and the log sheets.

5.2.5 Measurements

i) Plaque Measurements

All of the outreach centres utilise a computerised Kodak R4 records database which has its own unique plaque and bleeding chart system. This recording system was neither in line with those used within student teaching nor the usual method of recording measurements for oral hygiene based studies and as such was not considered suitable for the purposes of this study. After discussions with the Kodak R4 IT department it was concluded that the system could not be changed to suit DOOHS.

Clarkson researchers (Clarkson et al. 2009) completed their oral hygiene study measurements using the Loe and Silness' plaque and gingival bleeding indices (Silness 1964). The teaching within Dundee Dental School however follows the dichotomous scoring system of O'Leary (O'Leary 1972). For this study the O'Leary scoring system (plaque/bleeding present or absent on the four sites) was utilised to remain in line with the teaching in Dundee Dental School. This additionally had the benefit of student familiarity, with students having two years of experience of using this system.

ii) Bleeding Measurements

Bleeding was recorded using the same charting as the plaque measurements: the O'Leary system (O'Leary 1972). Students are taught in Dundee Dental School to record bleeding from the base of the periodontal pocket in order to record active sites for periodontal diagnosis. However, literature in the field and studies consulted for

the Cochrane review utilised the measurement of gingival margin bleeding as an indication of gingival inflammation. As such students were instructed to sweep the gingival margin and look for bleeding, checking back for any delayed bleeding sites. This was additionally detailed in the study training video (Chapter 6). As well as being the standard measurement, the additional benefit of recording marginal bleeding was that it was quicker to complete the measurements as this could be recorded at the same time as the plaque scoring.

5.2.6 Reported Oral Health Behaviours: Participant Questionnaire

Outreach patients reported their oral hygiene behaviours by means of validated questionnaires (Appendix 7). The baseline questionnaire was received as part of their patient information pack and completed at home prior to their next outreach appointment. This questionnaire had been previously validated for reporting oral hygiene behaviours by the 2009 oral hygiene study (Clarkson et al. 2009). The questionnaire was to be repeated at review to measure reported behaviour change. Full information on the construction and analysis of this questionnaire is in Section 8.2.2.

Patients who wished to participate in the study were asked to bring their completed questionnaire, in the envelope provided, to their outreach appointment. Participants who forgot their questionnaire but still wished to participate were able to complete a new copy of the questionnaire while sitting in the dental chair before the study measurements were taken. In these cases students were requested to leave the chairside area while the patient completed the questionnaire, so their presence did not influence the participant's answers. Participants requiring assistance to complete the questionnaire (for example if they had trouble reading), were assisted by a dental nurse. The completed baseline questionnaire was collected in a sealed envelope before the plaque and bleeding measurements were carried out. The participant ID number was written on the envelope which in turn was placed in a research collection box held at each outreach clinic.

5.2.7 Oral Hygiene Instruction Delivery

i) Provision of Equipment

In addition to the psychological delivery, the Clarkson (Clarkson 2009) study had provided powered toothbrushes to the intervention group. The Cochrane review investigating the effectiveness of manual versus power toothbrushes for dental health (Deery et al. 2010) identified a 3 month benefit of power toothbrushes over manual toothbrushes but only in relation to the use of rotation oscillation power toothbrushes and not any other powered toothbrush types. Use of power brushes was not a standard recommendation in outreach clinics and, at the time of the study, it was not possible to obtain powered toothbrushes from the manufacturers due to the economic climate. Therefore the DOOHS study was planned to replicate the Clarkson (Clarkson et al. 2009) methodology pertaining to randomisation and the psychological framework for oral hygiene delivery but with manual toothbrushes and two minute sand timers for the intervention group to replicate the times on the power toothbrushes. The oral hygiene method is explained within the Intervention Training section (section 6.5.3).

ii) Inclusion of Biomarkers

As current expert opinion (Chapple 2009) had suggested that the use of biomarkers may provide a method of enhancing compliance with oral hygiene behaviours, the additional use of biomarkers was planned within DOOHS. Gingival inflammation, with its obvious biomarker of bleeding, was used as an enhancement to the delivery of oral hygiene instruction for the interventional group.

Using the biomarker of bleeding had the added benefit of allowing the intervention group students to immediately feedback the findings from their charts to their participants and target oral hygiene instruction to appropriate areas of their participant's mouths. Observational studies both in the final year Integrated Oral Care (IOC) clinic and in outreach clinics had found that this feedback interaction was not common practice amongst the students. The tell-show-do component of the

psychological intervention was aligned with current teaching. Observation on the clinics demonstrated however, that oral hygiene instruction was rarely delivered in this manner by the final year students. The biomarker (Chapple 2009) and the ‘planning’ component (Clarkson et al. 2009), where the participant would plan when to clean and what to do if they become aware of bleeding (i.e. brush more carefully and effectively), were new additions to the observed oral hygiene instruction delivery for the students and for participants.

5.2.8 Sample Size

Lack of bleeding on gingival probing was taken as the measure of gingival health for this study. Bleeding from the gingival margin in the general population is on average, 30% of all sites according to the Scottish Health Survey 2009 (Scottish Government 2009). A 10% reduction in the number of bleeding sites was considered clinically significant (Clarkson et al. 2009). In order for the study to be sufficiently powered, a power calculation was carried out using online software used for cluster trials in health care from the Aberdeen University website:

<http://www.abdn.ac.uk/hsru/samplesize/ssc.exe>

Intra-cluster correlation was chosen to allow for the slight differences in the delivery of the intervention between practitioners. Dental studies accept an intra-cluster coefficient of 0.05 to be significant. DOOHS required 639 participants in each of control and intervention groups. Therefore a total of 1278 participants were required. The total number of Outreach patients which was to be recruited was aimed at 1500, in order to allow for a drop-out rate of approximately 20%. Given the numbers of patient contacts at the six outreach clinics, it was estimated that it would take 3-4 months for the students to recruit 25 patients each. Recruitment was planned to take place during the first semester of the final year.

5.2.9 Arrangement for Participant Reviews

Review appointments for DOOHS participants were carried out at three and six months to measure the short and longer term benefits of the oral hygiene instruction. The recruiting student was responsible for arranging the first review appointment at three months as well as any further appointments the participant required for dental care. The participant's usual outreach notes recorded that they had been enrolled into the study and the DOOHS icon, which had been arranged previously through the IT departments in each Health Board, was added to the participants' records in order to identify that they were involved in the study. This ensured that participants would not receive additional oral hygiene instruction during the study. Reviews were to be carried out by the dental students if the review appointment time was during term time, otherwise a member of outreach staff, or the research manager (KR) would carry out the review as appropriate.

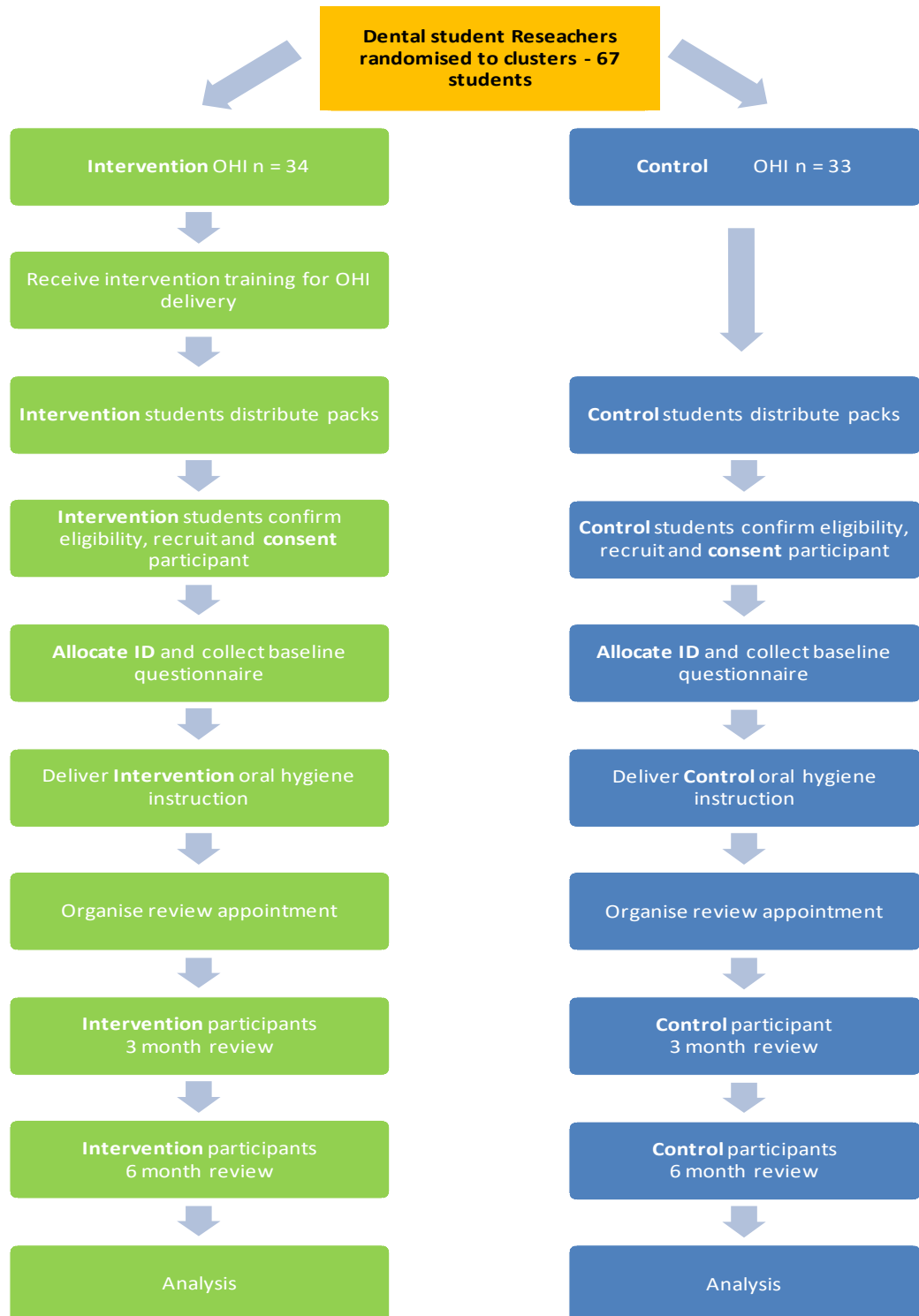


Figure 5.2: Schematic diagram representing student researcher group randomisation and participant flow through the Dental Outreach Oral Hygiene Study.

5.3 DOOHS Paperwork

5.3.1 Patient Information Packs

The patient information pack was to be distributed to every outreach patient attending for treatment during the recruitment phase of the study by the final year dental student researchers during their outreach attachments. The pack contained:

- A letter of invitation to the DOOHS (Appendix 8)
- An information sheet & leaflet (Appendix 8)
- The baseline participant questionnaire (Appendix 7)
- An envelope for returning the questionnaire

5.3.2 The Case Report Forms

Case Report Forms (CRFs, Appendix 9) formed the participants' records for the study. CRFs contained blank charts for recording measurements. These were removed after each research visit. In addition to the charts, the CRFs contained checklists to allow the students and supervisor to easily check that all the required research processes such as participant eligibility and consent had been completed. The dates of each visit by the participant for the study (research visit) were recorded on the front page to allow staff and students to easily view the timings for review visits. The CRF required each research visit to be signed off by an outreach supervisor and was designed to lead the students, and their supervisors through the research process for each participant.

Following the participant's baseline, three and six month visits, the completed plaque and bleeding charts were removed from the CRF and attached to the participant questionnaire recorded during each visit, before being placed in the research collection box for the research manager. This process ensured that the reviewing dentist would be unaware of the plaque and bleeding measurements from previous appointments.

5.3.3 Participant Baseline Questionnaire

There were three participant questionnaires: baseline, three months and six months (Appendices 7 & 9). Questionnaires had been previously used and validated by the Clarkson (Clarkson 2009) study. Additional questions were inserted to explore participant's views towards clinical research in dental outreach clinics.

5.3.4 The Site Files

Site files were maintained by the study manager (KR) and the outreach supervisors and trained dental nurses at each of the six sites. The site file contents had been advised by TAHSC and contained:

- Copies of permissions and correspondence for DOOHS
- Training logs for students and staff
- Research manager visit log and notes
- Log sheets
- Copies of questionnaires, the patient information sheet and letter of invitation
- Instructions and algorithms for DOOHS
- A copy of the instructional DVD

Consent form copies were stored in a separate file for convenience.

The trial master file was held centrally at the University of Dundee Dental School and maintained by the research manager (KR).

5.4 Necessary Permissions

Permissions for DOOHS were acquired as outlined in figure 5.3.



Figure 5.3 Schematic diagram outlining the process of required approvals for DOOHS

5.4.1 Dental School Board

As this study involved final year dental students during their outreach attachments, permission from Dundee Dental School was required. The final year students would collaborate with DOOHS as a requirement of the professionalism component of their final year. This approval was requested, and subsequently granted to allow their collaboration with the study. Involvement in clinical research was considered to be of potential educational benefit to the students by the dental school board.

Student responsibilities during the study were to:

- Distribute Patient Information Packs to outreach patients
- Discuss the study with potential participants
- Check eligibility
- Carry out consent procedures, in collaboration with trained outreach staff
- Allocate study identification code to participants
- Collect the participant questionnaire
- Record plaque and bleeding
- Deliver oral hygiene instruction according to group allocation

- Make participant review appointments
- Complete log sheets
- Carry out dental treatment for the participant as required

5.4.2 Sponsor

Clinical studies require a sponsor for insurance purposes. Approval from the University of Dundee as sponsor for DOOHS was required prior to seeking ethical approval. The University of Dundee made no requests for changes to the protocol and agreed to sponsor the study (Appendix 10).

5.4.3 Ethics

Research Ethics permission was sought through the Fife and Forth Valley Research Ethics Service. On receiving the application for ethics approval, the ethics committee invited the Chief Investigator (consultant with responsibility for dental outreach) and Research Manager (KR) to discuss the application with the committee. As this was the first study to involve outreach patients and the first time dental students had been involved in clinical research studies, it was considered essential to attend the meeting in order to answer any questions from the committee and further discuss the study.

On attending the ethics committee meeting for discussion of the study, two main topics evolved:

i) Role of Dental Students

The initial question about the study was to clarify the role of the dental students within the study. This discussion centred on the question of whether the students were considered to be participants or collaborators, and provoked lively debate and discussion around the table.

If students were considered participants, it would conflict with their required involvement as part of the curriculum. Participants have a choice to be involved or not however the dental students did not have a choice in which aspects of the curriculum they experience. As such this role of participant was not appropriate when involvement in DOOHS was a requirement of the undergraduate curriculum as previously sanctioned by the Dental School Board (section 5.4.1). The actual role of the dental students in the study was outlined to the ethics committee. The students, albeit under supervision, were in fact very much considered as clinical researchers and thus students should be regarded as collaborators in the study, not participants.

As collaborators in the study, the dental students and other trained research staff were registered co-investigators. Each outreach health board required a nominated Principal Investigator (PI). This was the senior outreach supervisor. Research curriculum vitae (CV's) and records of training were required for all co-investigators involved in clinical studies, therefore research CV's were required from all dental students in the final year in addition to the outreach supervisors and nursing staff trained to support the study.

ii) Participant Consent

The issue of consent was also discussed with the ethics committee. Dental students do not hold registration with a professional body and the committee agreed it was reasonable that participant consent should be carried out by the dental student in collaboration with a qualified, registered and GCP trained dentist or dental nurse. This impacted on the number of outreach staff requiring study and GCP training as required by the University of Dundee who was the sponsor of the study.

The ethics committee passed the study for approval after minor modifications to some questionnaire wording. Ethics approval was straightforward due to the attendance of the meeting by the Chief Investigator and research manager and ethics approval was granted quickly taking five weeks to complete.

5.4.4 NHS Research and Development

Following ethics approval, the protocol and study materials were passed to the centralised NHS Research and Development (R&D) department, who in turn distributed the application and study information/ materials to the four health boards involved.

In order to approve the study, each R&D department required:

- DOOHS Protocol
- IRAS Research Ethics Committee form
- CV from the Chief Investigator (Senior Dental Officer for Outreach)
- Ethics approval letter
- IRAS Site Specific Information form
- NRS-CC Certificate of compliance
- Site Specific Assessment Review (carried out by each R&D office)

Although there were no changes to the protocol or study paperwork requested, NHS R&D approval was the slowest to be granted taking around 12 weeks. This wait for approvals to be granted delayed the start of the study by 3 months (Appendix 11).

5.4.5 OHSAS

Occupational Health and Safety Advisory Service (OHSAS) clearance is required for any member of staff treating NHS patients. NHS regulations at the time of study legislated that staff could not work between different Health Boards without OHSAS clearance from each individual health board. Dental students were exempt from this regulation: they were not considered members of staff. Therefore, although the dental students could record measurements from participants in the study across all four health boards involved, the research manager (KR) required clearance from each individual health board involved in the study in order that review appointments could be carried out (if required) out with student term times. OHSAS clearance was

already in place for the Research Manager for NHS Tayside. This covered two outreach clinics: Springfield in Arbroath and Kings Cross in Dundee. NHS Fife sent out an OHSAS appointment within a fortnight of receiving the application and bloods were taken and clearance subsequently granted which allowed treatment of participants at the Cupar and Kirkcaldy clinics. NHS Highland insisted that an appointment was attended but accepted test results from NHS Fife. This allowed treatment of participants in Inverness outreach clinic. NHS Grampian were sent the required forms, however they failed to send an OHSAS appointment and as such; a hands-off approach was taken in Aberdeen outreach clinic.

5.5 Setting up DOOHS - Conclusions

Following the process of setting up DOOHS as outlined previously, a number of conclusions can be made. These are noted as below:

- Involving TAHSC and SDPBRN in the protocol development stages is beneficial for studies in dental outreach clinics.
- Dental School approval is required for dental student involvement in studies in dental outreach clinics.
- Sponsor approval is straightforward for low risk studies in dental outreach clinics.
- It is possible to gain necessary approvals for low risk clinical studies in dental outreach clinics.
- There is benefit in attending the ethics board meeting. This ensures that all questions can be answered and ethical approval obtained quickly.
- Students are considered collaborators not participants if they carry out the role of clinical researchers in outreach studies.
- Students consenting participants in clinical studies in outreach require the consent process to be completed in collaboration with a registered dental professional. This can be a research trained dental nurse.
- NHS R&D approvals take the longest to be granted.

- Clinical studies in dental outreach clinics should aim to have approvals in place the term preceding the start of the study to allow for delays in approvals.
- Although dental students are able to carry out clinical procedures such as measures for plaque and bleeding across health boards without specific OHSAS clearances, qualified dentists working across health boards are required clearance from each specific area.

Chapter 6: Training for the Dental Outreach Oral Hygiene Study

This chapter outlines the journey the Dental Outreach Oral Hygiene Study training took. It was anticipated that the training for a simple clinical study in dental outreach clinics would be straightforward as dental students are used to learning processes and procedures. There were links in place to allow the dental students access to Good Clinical Practice training delivered by experts in the area of clinical research. In practice, this training program prove to be unacceptable to the dental students and thereby important information was gained around the topic of providing training for clinical studies in the dental outreach setting.

6.1 Training Overview

6.1.1 Training Requirements

i) Training Aim

The aim of training for the Dental Outreach Oral Hygiene Study was to enable dental students to carry out research procedures and for the dental outreach staff to support the students with this and carry out review procedures as required. Therefore dental students and outreach staff required training in the following areas:

- Principles of Good Clinical Practice
- DOOHS protocol including inclusion/exclusion criteria
- DOOHS paperwork
- Recruiting procedures
- Reviewing procedures
- Intervention training for the intervention group

ii) Parties Requiring Training

Following discussions with the ethics committee and TAHSC, final year dental students at Dundee University and outreach staff were designated collaborators in DOOHS and as collaborators they required training. ‘Collaborants’ was the term used by the ethics committee to describe the position of the students carrying out the clinical research as they were not considered participants. Groups trained to deliver DOOHS included:

- Two final year groups of dental students (cohorts 1 & 2) (Sections 6.2 – 6.6), and
- Dental outreach staff (Section 6.7).

All parties were trained using a range of formats to cover an overview of the study, DOOHS protocol training and Good Clinical Practice (GCP) training for clinical studies. GCP training is mandatory for all clinical researchers involved in studies sponsored by the University of Dundee.

Training was documented in compliance with the Research Governance Framework (RGF), (Department of Health 2005). Registers were taken at training sessions and lists of staff and of students, trained and involved in DOOHS were held in the Trial Master File with copies in site files at each outreach clinic.

Research CV’s which contained the basic information required for RGF purposes (Appendix 12) were completed by staff and students involved in DOOHS.

6.1.2 Training Delivery

Training for clinical researchers (both staff and students) involved in DOOHS was delivered in a variety of formats:

Students:

- An introductory overview lecture (Section 6.2.1)

- A Good Clinical Practice (GCP) training session (Section 6.3)
- A Training film (Section 6.4)
- A lecture on DOOHS protocol training (Section 6.5.)
- An intervention group training session (Section 6.5.3)

Staff:

- Combined DOOHS protocol and GCP training (Section 6.7)

All Training was delivered to the first cohort of dental students by the author, with the exception of the Good Clinical Practice training afternoon, which was delivered by the Tayside Academic Health Science Centre (TAHSC). DOOHS protocol information was delivered in lecture format. Small group training tutorials were used in the delivery of protocol as well as intervention and control training.

Due to the 12 week delay in obtaining NHS Research and Development approval a second cohort of dental students had to be trained (cohort 2). They received their introductory lecture, DOOHS protocol and GCP training as a condensed lecture which covered details required for their conduction of participant review visits all tuition was provided by the author.

6.2 Student Training

Dental students, as collaborators in clinical research, required full training as clinical researchers. DOOHS protocol and Good Clinical Practice training was therefore delivered to the two consecutive final year groups of students (cohorts 1 & 2) who would be involved in the study. A total of 137 dental students were trained over the two academic years. The feedback from the first year group of 65 students (cohort 1) with regard to the DOOHS protocol training informed the training of the subsequent final year group (cohort 2). All student training was carried out within the Dental School.

The first week of the academic year (week commencing 01/09/2010) was the only week during the final year when all dental students were in available at the same time in Dundee. This week was used to welcome the students into their final year,

deliver necessary lectures, and provide information regarding their final year timetable, including outreach clinic arrangements.

At this time, DOOHS was waiting for final approvals from NHS Research and Development (R&D) departments. The introductory lecture on clinical research in dental outreach and the Good Clinical Practice (GCP) training had to be delivered at this time despite the final approvals not being in place, due to timetabling.

6.2.1 Student Introductory Lecture to Clinical Research in Dental Outreach

A short introductory lecture about clinical research in outreach was delivered to the final year. The aims of this lecture were to:

- Introduce the importance of clinical research to the students
- Explain the reasoning behind delivering clinical study in outreach

The lecture was delivered by the author (KR) with the support of the necessary academic member of staff with responsibility for the dental outreach programme. This lecture was attended by the entire year of students within Cohort 1. A register was taken for study documentation purposes. The lecture took 30mins. Students were reminded of the requirement to attend the GCP session the following afternoon.

6.3 Student Good Clinical Practice (GCP) Training

6.3.1 First Cohort of Students' GCP Training

Tayside Academic Health Science Centre (TAHSC) agreed to deliver the students' training in GCP on behalf of the sponsor. This was to be the first time that they had delivered training to a group of undergraduate students. An afternoon was put aside for this purpose.

GCP training consisted of a series of lectures delivered by three lecturers from TAHSC over a three hour period. Lectures covered topics which were considered essential and relevant to researchers delivering clinical trials and included the following:

- Research ethics
- The Research Governance Framework (RGF)
- Consent for clinical studies
- Data protection

At the end of the afternoon, TAHSC distributed their feedback questionnaire (Appendix 13) to the students. These questionnaires had been designed by TAHSC to gather information on how the training had been received by the students with a view to improving future training delivered by the group.

6.3.2 First Cohort of Students' GCP Training Feedback

All 65 final year students attended the afternoon of training. There was no break during the afternoon. The length of the session was considered too long by the students. As the information was delivered as didactic lectures, there was little opportunity for student interaction. The exception to this was the research ethics lecture during which the lecturer posed questions directly to the students in order to engage the audience. She also explained principles using easily understood analogies. This lecture was received more favourably by the students. The other lectures were heavy in terms of content and the students struggled to focus, becoming restless towards the end of the training afternoon. Fifty nine questionnaires were returned to TAHSC from the 65 distributed.

The questionnaire was titled *“Introduction to Good Clinical Practice for ‘non-drug’ and CE-marked device studies”* (Appendix 13) and feedback from this is displayed in Table 6.1.

Table 6.1: Dental Student Feedback to TAHSC after GCP training

Question	Student Response		
Did you receive sufficient briefing about the course today?	Yes 33	No 26	
Comments	“Thought course would be study specific.” (3 responses) (2 responses) “Unsure of the learning outcomes.”		
Overall did the course meet your learning needs?	Yes 14	No 18	Partially 24
Comments	“Too much information.” (9 responses) “Irrelevant.” (3 responses) “Difficult to understand.” (1 response) “Helped understanding.” (1 response)		
What subject was the most useful to you?	“Consent” (21 responses) “Ethics” (17 responses) “All irrelevant” (5 responses) “History of clinical studies” (3 responses) “Role in the study” (2 responses) “Green goblin – ethics story” (1 response)		
What subject was not useful to you?	“Everything/too much information.” (12 responses) “Documentation” (4 responses) “TAHSC”, “Design”, “Tissue bank info” (all 3 responses) (2 responses) “Governance” (all 1 response) “Protocol”, “monitoring”, “ethics”.		

Question	Student Response
Are there any areas you would like further training on?	<i>"No!"</i> (9 responses)
	<i>"Study specific information."</i> (7 responses)
How can we improve this GCP course?	<i>"Shorten the course."</i> (23 responses)
	<i>"Make relevant to the study."</i> (17 responses)
	<i>"Improve presentation."</i> (13 responses)
	<i>"Have a break during the afternoon."</i> (7 responses)
	<i>"Simplify or make easier to understand."</i> (3 responses)
Rate the overall usefulness of the course.	<i>"Not at all useful."</i> (18 responses)
	<i>"Not useful."</i> (20 responses)
	<i>"Uncertain."</i> (13 responses)
	<i>"Somewhat useful."</i> (6 responses)
	<i>"Very useful."</i> (1 responses)
Have you received any GCP training before this course?	<i>"No."</i> (56 responses)
	<i>"Yes."</i> (3 responses)
Additional comments	<i>"Needed a break."</i> (10 responses)
	<i>"Waste of time/irrelevant."</i> (9 responses)
	<i>"Too much information."</i> (9 responses)
	<i>"Course too long."</i> (4 responses)
	<i>"Too difficult."</i> (4 responses)
	<i>"Dry."</i> (1 response)
	<i>"Improved my understanding."</i> (1 response)
	<i>"I can see potential in this course."</i> (1 response)

6.3.3 Student GCP Training Discussion and Conclusions

The GCP training session was not popular with the students. The afternoon session was viewed as too long and the students needed a break during the three hours. Students reported to be overwhelmed with the amount of information and they reported to be unsure of the relevance of this information to DOOHS. The lecturers were not used to delivering GCP training to undergraduates with little understanding of research. However, the topics which were already familiar to the students, such as ethics and consent, were received more favourably and considered helpful by the students. The GCP afternoon generated a lot of negativity towards the clinical study and failed to enthuse students towards clinical research.

Lessons were drawn from this and in conclusion, GCP training for final year dental students should:

- Be condensed in terms of content and time
- Be delivered in a manner which encourages student interaction
- Be delivered in a way which is closely tailored to whichever study they are collaborating with so students can relate to the content
- Ensure the key points are illustrated with examples from the clinical study they will be delivering so they can understand the relevance

The conclusions from the dental student feedback with regard to the first cohort training session were used to help develop a revised GCP training for the following year group of dental students and the outreach staff training.

6.4 Training Film (Initial Visit)

A short film (Appendix 14) was produced by the author (KR) illustrating in detail the initial research visit where a student would recruit and consent a participant for DOOHS and carry out the initial clinical measures. This was filmed at Springfield Outreach Clinic, Arbroath and covered:

- Discussing DOOHS with an outreach patient
- Confirming participant eligibility for DOOHS
- Consenting a participant
- Allocating a research identification number to the participant and subsequently applying this to the paperwork
- Completing the CRF
- Collection of the questionnaire and applying identification
- Carrying out initial clinical measures
- Completing and calculating plaque and bleeding charts

This film was used for both student and staff training. Hard copies were retained within the site files for reference with additional availability online. It was considered important that the methods in the video were being carried out in an outreach clinic so it would appear realistic to the students and staff. The actor in the video was from out-with the dental school, and from the student and staff viewpoint, a ‘real’ outreach patient. An outreach nurse played the role of trained research dental nurse.

6.5 Students DOOHS Protocol Training

After the GCP training afternoon was so poorly received, it was decided appropriate for the remaining study information to be delivered in short tutorials to encourage engagement with the research.

The timetable for the final year was complex. Six outreach clinics and clinical attachments in Dundee Dental School resulted in two groups of students not being present in Dundee each week due to blocks of outreach attachment in Inverness and Aberdeen.

Small group tutorials were considered an appropriate delivery method for DOOHS protocol training. As the final year were already split into tutorial groups, student tutorial leads were approached and asked if they would allow one hours tutorial to be

given to up for DOOHS protocol training. The leads agreed. Protocol training was completed during the first semester. The tutorial format was less formal than the GCP training and it was hoped that, by providing students with an opportunity to discuss their role in DOOHS and to view the paperwork, they would engage with the clinical study.

This tutorial was split into:

- DOOHS protocol training for all students
- Intervention training for the intervention group only

6.5.1 Students DOOHS Protocol Training Tutorial

The tutorial started with a power point presentation clarifying the definitive details of the protocol. Students were each given a copy of the Case Report Form (CRF) for information and discussion. There was next a discussion time with the focus on paperwork for participant recruitment. Students finally viewed the training film to see how the delivery of the research would happen ‘in real life’. Students were informed of the help folders with instructions which would be available in each of the outreach clinics. These instructions additionally contained photographs of protocol stages. As the final NHS R&D permissions had still not been received at this point, students were advised that they would be told when the study was to begin. It was anticipated that this would be within a few weeks. Concern was expressed by those involved in the organisation of the study that student collaborators would forget or further disengage with the study during the period.

6.5.2 Student Allocation to Control and Intervention Groups

The final year students were allocated randomly to deliver either control or intervention oral hygiene instruction. Students were informed of their research number and their group allocation by sealed letter in advance of the training tutorial. The author (KR) required knowledge of student groupings, due to the requirement

for training of the intervention group; however remained blind to the student researcher numbers to later allow blinded data analysis.

The second half of the protocol training tutorial was used to deliver the intervention training.

6.5.3 Intervention Group Training

After the protocol training, the control group students were requested to leave the tutorial room. This left the intervention students in each group. Training would enable students to provide oral hygiene instruction, as per Clarkson (Clarkson 2009), but with the added use of biomarkers.

The 2009 Clarkson study utilised a five minute oral hygiene instruction delivery which was framed by combining the psychological theories of Bandura and Gollwitzer (Bandura et al. 1991; Gollwitzer 1999).

Bandura's Social Cognitive Theory (Bandura et al. 1991) utilised the Tell-Show-Do format for influencing behaviour change. It theorises that behaviour change for an individual is dependent on their self-efficacy. The self-efficacy of a patient in relation to oral hygiene is measured by their reported confidence in carrying out oral hygiene practises. In order to increase a patient's confidence in oral hygiene they need to carry out the oral hygiene behaviour, view instruction on how to carry out this behaviour and receive encouragement from the dental professional. How the patient feels after this also impacts on their confidence in carrying out the behaviour (Clarkson et al. 2009).

Gollwitzer (Gollwitzer 1999) proposes that an action plan is required which includes when the behaviour should be performed. This plan would have a cue as to when the patient should to perform the behaviour. In relation to oral hygiene instruction, this action plan could be, for example, to clean teeth before bed or after a meal. For DOOHS this action plan was to clean teeth twice daily and more carefully if the

patient became aware of bleeding from their gums. The format utilised for the intervention group in DOOHS is shown in Figure 6.1.

Students in the intervention group would use the bleeding charts they recorded during the baseline measures to target the oral hygiene instruction for the participants. Participants in the intervention group were informed of their gingival bleeding as gingival bleeding is considered a biomarker for gingival disease. The intervention group students completed their instruction with a plan for participants to clean more carefully and regularly in areas where they were aware of gingival bleeding. The use of biomarkers and planning strengthened the usual ‘tell-show-do’ oral hygiene instruction delivery which was unusual teaching at the time.

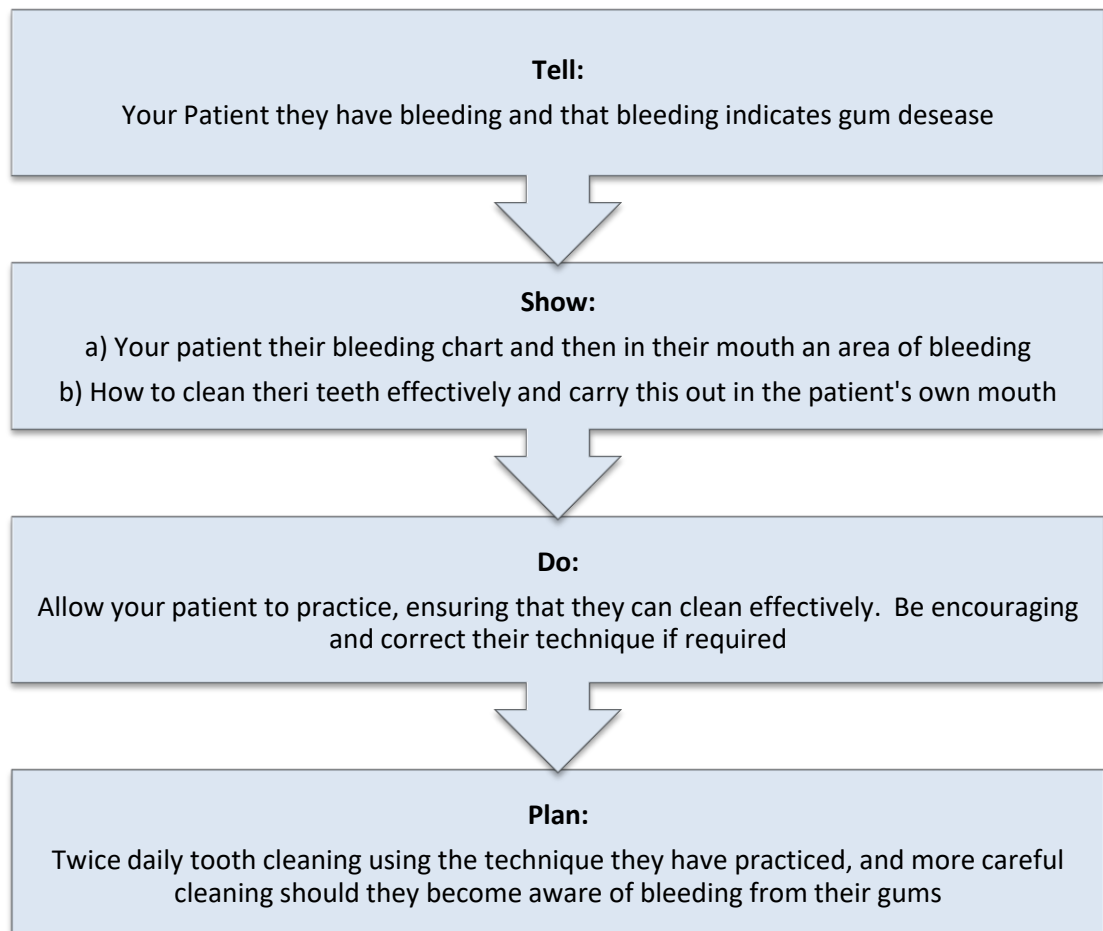


Figure 6.1: Schematic diagram detailing DOOHS oral hygiene delivery format for the intervention group.

Students in the intervention group were instructed to use visual aids in the form of the bleeding charts which they had recorded and also advised instruction was to be completed within the participant's own mouths (Figure 6.2). Intervention group students followed the instruction, outlined in Appendix 15. This informed the patient of their chart results, showed participants where and how to clean and allowed the participant to practise, corrected their technique and ensured the patient had a plan of how to target their cleaning. Participants were then given a new toothbrush. Participants in both control and intervention groups were given replacement toothbrushes at three and six month review visits. The intervention group participants were additionally given two minute sand-timers to replicate the two minute timer which were in built on the power brushes used by Clarkson 2009.



Figure 6.2 DOOHS Intervention



Figure 6.3 Participant practicing technique demonstration

The intervention group training additionally explained the evidence base behind the interventional method of oral hygiene instruction delivery. They received an 'intervention pack'. This pack consisted of:

- a copy of the intervention film which contained slides and photographs explaining the enhanced oral hygiene instruction technique,
- a step-by-step photo hand-out, and
- several two-minute sand-timers in a sealed brown envelope which would fit into their final year logbooks.

Students viewed the instructional video during the tutorial time with the author and had opportunity to discuss the enhanced oral hygiene instruction and to ask questions.

6.5.4 Control Group

The control group of dental students was noted to provide oral hygiene instruction and/or advice as they usually would on the outreach clinics, without the use of any prompt sheets. For some students in the control group this simply involved providing verbal discussion with the patient while others demonstrated techniques in the participant's own mouth whichever was the usual practice for that student. The control group were reminded that their oral hygiene instruction delivery should comprise whatever they would usually do or regarded appropriate for their recruited participants. If they would usually only deliver verbal oral hygiene instruction, it was important that they did not change their method. However if they usually took a very detailed approach, then this was also acceptable. Students in the control group received no additional instructions or guidance.

Participants in the control were given new manual toothbrushes at baseline and replacement toothbrushes at three and six month review visits.

6.6 Second Cohort Training

As a direct result of the feedback received following the TAHSC GCP training afternoon, the second cohort of dental students received a revised delivery of both the GCP training and the DOOHS protocol training directly from the author (KR). This comprised a condensed training incorporating both subjects, and in particular,

the GCP training was reduced in terms of content to provide only information relevant to the DOOHS study. This revised training was in line with that provided to the Outreach staff and was presented in a tutorial style. Cohort 2 did not require to be trained in the participant recruitment stage as they were only carrying out participant reviews and not consenting new patients for the study.

6.7 Outreach Staff Training

Training was provided to all outreach supervisors and dental nurses who worked in and supported the outreach clinics. Training was essential for these groups within the clinics in order that the students would be adequately supervised and supported during their delivery of DOOHS. Dental nurses and outreach supervisors trained in the study methodology were research collaborators and were listed as co-researchers for paperwork purposes. All principal investigators (senior outreach supervisors) were trained. Training registers were taken and a research CV was completed by each member of staff. Outreach staff training took place in each outreach clinic.

6.7.1 Delivery of Outreach Staff Training

To arrange training, the senior outreach clinician at each of the six established outreach clinics was initially contacted by email to introduce and explain DOOHS and offer training for staff. It was emphasised that their support would be essential to the students during the study. It was suggested that both supervising dentists and dental nurses attended training. GDC registered Dentists and dental nurses who had been trained in GCP and DOOHS protocol, were eligible to countersign consent forms for dental students. Other staff with protocol training included reception staff and trainee dental nurses in order that they could support the students in other ways, for example handing out information packs, arranging participant appointments and helping with other paperwork.

Staffs were informed that the training session was expected to take around 1.5 - 2 hours. Four of the clinics, Cupar, Springfield, Kings Cross and Aberdeen, received training during a dedicated afternoon session, which had been agreed by their

clinical directors. Two clinics, Kirkcaldy and Inverness, opted to have their session over an extended lunch hour. The location of the different staff groupings that were trained are listed below:

- Aberdeen: two outreach supervisors
- Springfield: two outreach supervisors, three outreach dental nurses and one receptionist
- Kings Cross: two outreach supervisors and two outreach dental nurses
- Cupar: one outreach supervisor and two outreach nurses
- Kirkcaldy: two outreach supervisors and one outreach dental nurse
- Inverness: initially two outreach supervisors and thereafter a total of nine outreach dental nurses over two further training dates

6.7.2 Outreach Staff GCP & DOOHS Protocol Training

As a direct result of the negative feedback from the dental students regarding the format of their GCP training, the delivery of this aspect of staff training was redesigned in collaboration with TAHSC. GCP training was subsequently reduced in terms of content. To ensure the training was directly relevant, GCP information was delivered around the DOOHS protocol.

GCP training would not usually be delivered to clinical researchers in this format, however as the training was to be delivered only to outreach staff, and these staff would only be delivering DOOHS and not any other clinical studies in that year, it was considered appropriate to make the training DOOHS specific.

Staff training took place between September and November 2010. Inverness subsequently requested two additional dates for nurses to be trained, due to a changeover of nurses in the outreach clinic. This additional nurses' training was completed in March 2011. Staff training was delivered as a Section 63 course. The approval for verifiable CPD and Section 63 course status was granted by NHS Education Scotland (NES). Those attending the course were awarded 2 hours of verifiable CPD.

All outreach staff training was carried out as small group tutorials. Training took place at each outreach site. The Inverness outreach clinic had a designated student tutorial room which could be booked specifically for training and this had projection facilities. The Springfield and Aberdeen clinics had specific meeting rooms which were made available; however there were no projection facilities at these clinics. The Cupar and Kirkcaldy clinic training sessions took place in staff rooms while, in the Kings Cross outreach centre, the outreach clinical area was used due to lack of availability of a private room.

Where there were no projection facilities a laptop was used for the presentation. This worked well with the small groups involved. The presentation started with protocol information and the GCP implications around each aspect of the protocol and the study paperwork. Copies of log sheets and the CRFs were available for staff to examine during this session. In later presentations the site files were available for discussion. Staff viewed the film of participant recruitment and baseline measures. They were informed that the film was available on the University of Dundee website in addition to the hard copy within the site file.

The first two staff training sessions were conducted together with a manager from TAHSC to ensure they were satisfied with the GCP delivery. Subsequent presentations and training sessions were conducted solely by the author.

At the end of the training session staff completed a short feedback questionnaire (Appendix 16) relating to fulfilment of the course aims and objectives, as a requirement of the Section 63 course.

6.7.3 Additional Attendees

In Inverness, dental therapy students from the University of Highlands and Islands (UHI) also worked within the outreach clinics and as such were asked to attend a tutorial regarding DOOHS so they would be aware of the implications of them providing treatment for participants within the study. In this regard, these students

were instructed not to provide further oral hygiene instruction to participants during the study.

6.7.4 Outreach Staff Training Feedback

The staff training sessions were interactive and informal. Staff received CPD certificates at the end of their training session. A total of 29 staff were trained for the study. Twenty-three out of 29 feedback forms were returned. The shortfall in returns was due to dental nurses leaving training early due to clinical commitments and failing to return the questionnaire at a later date. Table 6.2 shows a summary of the responses received in connection with the questionnaire.

Table 6.2: Feedback from a questionnaire administered following the DOOHS Section 63 course for dental outreach staff

Demographics of staff returning feedback questionnaires	Dentist	Dental Nurse	Other support staff	Missing
	9	8	2	4
The following objectives of this course were met:				
1. Good Clinical Practice in relation to clinical research.	Yes: 22		Partially: 1	
2. Understanding of DOOHS.	Yes: 20		Partially: 3	
3. Understand how to support students during DOOHS.	Yes: 21		Partially: 2	
4. How to consent patients for DOOHS.	Yes: 21		Partially: 2	

	Excellent	Good	Average	Poor	Missing
How would you rate the overall content of the course?	8	15			
How would you rate the course presentation and design?	11	12			
How would you rate the relevance to your educational needs?	6	12	2		1
How would you rate the length of this course?	22	1			
What was the best feature of this course?	<i>"Video"</i> <i>"Interesting and detailed"</i> <i>"Slides"</i> <i>"Group size"</i> <i>"Explanation of the research process"</i>			(10 responses) (3 responses) (3 responses) (2 responses) (2 responses)	
What would you have changed?	<i>"Nothing" or blank</i> <i>"Show paperwork first"</i>			(22 responses) (1 response)	
General comments	<i>"Informative"</i> <i>"Relevant"</i> <i>"Good presentation"</i> <i>"Easy to understand"</i> <i>"Quite a lot of admin"</i> <i>"Would have been good to see the paperwork first"</i>			(4 responses) (2 responses) (2 responses) (1 response) (1 response) (1 response)	
Would you recommend this course?	Yes: 20		No: 1		Missing: 2

6.7.5 Outreach Staff Training Discussion and Conclusions

Outreach staff training produced favourable feedback. The revised training benefitted from the cohort 1 student GCP feedback which led to training being reduced in length and content, and put into context with reference to the actual clinical study the staff would be involved with (DOOHS). Staff found the length of the training acceptable and remained engaged during each training session. The small group sizes allowed training to be completed in a friendly manner with much discussion and interaction. By the time staff training was underway the paperwork for the study had been finalised. This allowed staff to view and discuss the paperwork which they would help the students to complete during the study. At one outreach clinic, several training sessions had to be delivered to allow for turnover of dental nurses who rotated between the different community clinics. It would have been beneficial to have had a list of all staff who would be supporting the clinic in advance, to allow training to be better organised. Staff were keen to accrue the CPD points. CPD points were especially welcomed by the dental nurses. Overall, staff feedback was positive, with a few suggestions which could be used for any further staff training in dental outreach clinics, such as viewing the paperwork beforehand and extending the session if required. Conclusions from the staff training were as follows:

- Outreach staff training, within clinical hours, was dependent on the goodwill of Clinical Directors
- Outreach nurses may rotate through the clinic therefore research training had to be repeated during the year
- A list of all staff supporting the students within a particular health board was desirable to help ensure all appropriate staff received training
- Outreach staff would attend training for clinical research studies in outreach
- Enabling staff to gain verifiable CPD for clinical research training for outreach studies was desirable, especially for dental nurses
- Combining GCP and study protocol training was of benefit in enabling staff to understand the relevance of GCP in relation to this particular study

- Staff benefited from having all research paperwork on site before the training was carried out
- Training films were favourably received by dental outreach staff as an adjunct to training

6.8 Training for Clinical Research Studies in Dental Outreach: Discussion

Dental student training for DOOHS was delivered in advance of the final paperwork being approved. The reason for the delivery of the training to the students at that time was the fact that this was the only opportunity to speak to the whole year group together due to timetable restrictions. The delivery of the training therefore occurred before the final paperwork had been approved and printed for the study and also four months in advance of the eventual start of the study. The early delivery of the training resulted in two problems.

Firstly, the final paperwork had not been approved at that time and therefore the students were only able to view drafts of the CRFs and log sheets during their training tutorials and lecture. This meant that when the students started their participant recruitment, the paperwork looked slightly different from what they had previously seen. This may have been confusing for some students and unfortunately gave the study a less 'professional' appearance.

Secondly, the delay between the delivery of training and the start of participant recruitment meant the students could not immediately put into practice the procedures and methodology which had been covered in the lectures and may have been a reason why the log sheets were variable in the standard of their completion.

The delay in the start of the study was favourable for staff training as there was more time for staff training development and the delay allowed the results of the students GCP feedback to be utilised to revise the way in which GCP training was delivered to outreach staff and the following year group of dental students.

The delivery format of the GCP training to the first year group of dental students (cohort 1) was very unpopular. The training was delivered over a long and arduous afternoon with little opportunity for questions or interaction. The training delivered by TAHSC was a generic format, designed for clinical researchers who have no choice other than to complete the training in order to carry out their work. The dental students had no previous knowledge of clinical research and saw the afternoon as an overload of irrelevant information. This had the unfortunate effect of putting many of the students off clinical research, and therefore set up a barrier between some of the students and DOOHS.

The experience of the first cohort of students benefitted dental outreach staff. After the feedback, the delivery was closely examined and the reasons for the poor feedback considered. Discussing GCP with TAHSC it was agreed that as the dental outreach staff would likely only be undertaking DOOHS and not any other clinical studies, it would be acceptable to tailor the GCP information specifically to the study. This allowed the principles of GCP to be woven around the methodology training and lightened the delivery, making it very relevant to DOOHS and allowing the outreach staff to relate their GCP knowledge to specific aspects of DOOHS paperwork. Much greater attention was placed on methodology, linking this to consent and ethical issues around clinical research and highlighting data protection issues. Clinical governance was discussed in relation to the site file. The following year group of dental students (cohort 2) received the same training as the dental outreach staff. They did not however require to be trained in the participant recruitment stage as they were carrying out participant reviews and not consenting new patients for the study.

Outreach staff training was reliant on the goodwill of their Clinical Directors. This meant that in some health boards outreach staff were given an afternoon out of clinics in order to attend training, whereas in other health boards outreach staff admin time or a mix of admin time and a lunch hour was used to attend the training.

The training of all staff groups was carried out in a small tutorial format and lasted, on average, two hours. The small groups allowed outreach staff to closely handle

DOOHS paperwork and the site files, asking questions as they wished, and also allowed the author to gauge whether staff appeared confused and clarify points as required. The sessions were very much interactive and staff gave favourable feedback for the training. Outreach staff had the added benefit of accruing CPD for the training, thereby receiving immediate 'reward' for attending and participating. This was something which the students could not benefit from. The CPD points made the training especially popular with the dental nurses.

Outreach staff overall were happy with the length of the course and one member of staff viewed that the training session had in fact been too short. Staff indicated that they felt the course objectives had been met overall. The delivery of the course was well received in relation to the content and relevance to training needs. Most outreach staff indicated that they would not change anything about the course. One staff member suggested that the paperwork be shown at the beginning of the session, and this was then changed for further outreach staff training sessions.

Outreach staff viewed the DOOHS training film favourably. This was also in agreement with the dental students who indicated later on through their post-study questionnaires that the film was the most useful part of their training. Outreach staff were also happy with the presentation slides and the group size. In the general comment section staff explained that they found the course relevant and informative.

Overall, outreach staff indicated that they were looking forward to the project. One member of outreach staff viewed the admin as potentially time consuming.

6.9 Training for Clinical Research Studies in Dental Outreach: Conclusions

- GCP training is better received by outreach staff and dental students if the concepts are communicated within the format of the study they will be carrying out
- Small tutorial groups are favourable, compared to large group lectures, for clinical research training for studies in outreach
- Outreach staff appreciate gaining CPD for clinical research training

- While Clinical Directors are supportive of staff development and allowed training time within clinic hours, this is variable between Health Boards
- Dental student training requires careful consideration if students are to be enthused towards a particular research study
- Clinical research training for studies in outreach is time consuming due to the geographic spread of the clinics and the availability of outreach staff and dental students over the academic year

Chapter 7 – Delivery of the Dental Outreach Oral Hygiene Study

This chapter discusses the delivery of the Dental Outreach Oral Hygiene Study (DOOHS). This includes the recruitment of participants to the study (Section 7.1) and the review visits at three and six months (Section 7.2). Issues in delivering the study, such as numbers of participants recruited, retention of participants and how the outreach clinics managed with the clinical research study delivery are presented and discussed in this chapter. (Full DOOHS results are presented and discussed in Chapter 8).

The aim addressed in this chapter with regards to delivering DOOHS is:

- To investigate the practicalities of delivering clinical research in dental outreach.

This aim was addressed through two primary objectives. These were:

1. Explore recruitment and retention for a clinical study in the dental outreach clinics.
2. Identify barriers and facilitators towards clinical research in the dental outreach clinics.

A secondary objective of the clinical study: to test the effectiveness of the oral hygiene instruction delivery on the periodontal health of dental outreach patients; is discussed in Chapter 8.

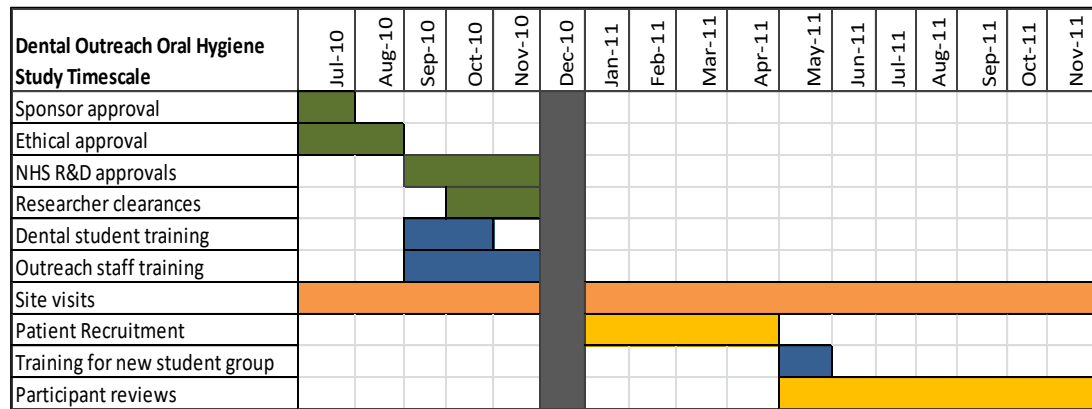
7.1 Participant Recruitment

The research objectives of the participant recruitment stage in relation to the feasibility of clinical research in dental outreach were to determine whether:

- i. outreach clinics would distribute information about a clinical study,

- ii. outreach patients would wish to participate in a clinical study during their dental appointments,
- iii. dental students would recruit participants to a clinical study, and the recruitment rates achievable,
- iv. dental students could carry out consent procedures for clinical studies in outreach,
- v. dental students could record simple measures for a clinical study into oral hygiene delivery,
- vi. dental students could deliver a simple clinical study intervention,
- vii. baseline paperwork for a clinical study could be completed, and
- viii. the level of support required for clinical studies in outreach during the recruitment phase would be adequate.

Approvals for DOOHS were in place by 2nd November 2010, however this left only six weeks of term before the students' Christmas break. This timing also coincided with the worst winter in many years and snow resulted in travel difficulties for patients at some of the outreach clinics. It was therefore decided that recruitment for DOOHS would be better to commence in the spring term, January 2011. This allowed time for the delivery of study materials to the clinics and also reduced the time between distributing study information and the return visits by participants for recruitment to DOOHS. The timing of the implementation of the study and the time taken for approvals to be granted is shown in Figure 7.1.



Key	
Approvals	█
Training	█
Study delivery	█
Outreach clinic visits	█

Figure 7.1: Gant chart, displaying the timing of events during the Dental Outreach Oral Hygiene Study

During training visits to the Outreach clinics, the set-up and environment of the clinical area was discussed with outreach staff in relation to the delivery of the study. Clinics had different availability of space for storage of research materials. The organisation of these materials at individual clinics was the responsibility of the outreach staff. After staff training and the final printing of paperwork, the following items were delivered to each outreach clinic:

- 1 site file
- 50 Case Report Forms
- 50 toothbrushes
- 6 spare timers for the intervention students
- Patient Information Packs
 - Aberdeen: 200 packs
 - Cupar: 125 packs
 - Inverness: 200 packs
 - Kings Cross, Dundee: 125 packs
 - Kirkcaldy: 125 packs

- Springfield, Arbroath: 200 packs
- 1 DVD with the training film detailing participant recruitment
- 50 participant consent forms
- 1 set of instruction sheets and flowchart detailing patient recruitment procedures
- 1 set of log-sheets and a small folder in which to keep current log sheets
- 1 research collection box

7.1.1 Pack Distribution and Recruitment of Participants

Patient information packs were distributed to patients between January and March 2011. On the first day the study commenced, outreach clinics were reminded, by phone call, that patient information should be distributed to every patient with some natural teeth who attended for an appointment. Dental students were informed of the start date by an announcement on the University of Dundee student Virtual Learning Environment (VLE), BlackBoard™.

After distributing patient recruitment information, the dental students recorded in the patient's notes that they had received this study information. This was to enable the next treating student to formally recruit the participant to the study. Recruitment took place from 28th January until the 21st April 2011.

All clinics distributed information to patients with one exception. In that particular clinic the study materials could not be located by staff. At this clinic, the nurse who had received the study materials had, unfortunately, left them locked in her office and was on annual leave when the study commenced. Once the materials were located (under a desk in her office), distribution of information commenced thereafter.

By 21st April 2011 a total of 165 participants had been recruited to DOOHS. Of these, 88 were in the control group and 77 in the intervention group. Recruitment was stopped at this stage as it was the end of the outreach attachment for the first cohort of students.

7.1.2 Monitoring of DOOHS during Recruitment Stage

Research Governance Framework (Scottish Executive 2006) for clinical research studies requires clinical research centres to be monitored at minimum intervals of one month. During the recruitment of participants, and in the initial months of DOOHS, the outreach clinics were visited more frequently to ensure adequate support for the final year dental students and outreach staff. Sites received a minimum of two sessions of support every two weeks. This was increased for sites closer to Dundee where students attended on day attachments. These sites were suitable for single session visits, allowing two sites to be visited in a day.

During monitoring visits, study paperwork was checked. These checks included ensuring the participant identification numbers were recorded correctly on the CRFs and cross checking these with log sheets. Research paperwork was removed from the collection boxes on a monthly basis.

Site visits provided an opportunity to discuss, with each clinic, their progress in participant recruitment and to help with any paperwork issues. In addition, these visits provided an opportunity to view the students' delivery of the study and answer any questions the students had regarding the study. There was additional email communication with outreach staff and dental students and a telephone line for clinics and DOOHS participants to facilitate answering any questions.

In order to fulfil the aim of testing the practicalities of delivering a clinical research study in dental outreach clinics, notes were taken during the study visits and also after any email or telephone contact with the clinics during the study. Notes were also taken of any informal discussions with outreach staff, students and outreach patients to gain additional insight into the delivery of clinical research in Dental Outreach.

How the sites were coping with the delivery of the research was considered after discussions with staff and through examination of the research logs and Case Report Forms. The organisation of the research materials at each clinic was also recorded.

The barriers experienced by the staff and students in relation to completing the research paperwork varied from site to site and the reasons for these were discussed with staff and students. Advice was given to people as and when requested or required. Photographs were taken at some sites to record examples of the organisation of the research materials. Consideration was given to the differences between the clinics and factors which could be impacting on their delivery of clinical research.

7.1.3 Recruitment of Participants Results

A total of 53 site visits were made. During the participant recruitment phase it was apparent that the outreach clinics had different approaches to the study. Four of the clinics came across as very enthusiastic. These particular clinics ensured that the students distributed paperwork and remembered to recruit participants. Two of these clinics had outreach nurses who took responsibility for the study paperwork and arranged materials in a manner that the students could easily locate what they required. The other two clinics had enthusiastic outreach supervisors who took responsibility for organising the study materials and the study paperwork. A further two clinics were less enthusiastic and these were the larger outreach clinics. At these outreach clinics the study materials were harder to locate, lacking a designated area. One clinic, as previously mentioned, had left the patient information packs under a desk in a locked room where they could not be accessed by staff or students at the start of participant recruitment to the study. These two larger clinics subsequently struggled the most with paperwork completion during the recruitment phase. Table 7.1 shows the division of paperwork responsibilities during DOOHS.

Table 7.1: Division of paperwork responsibilities between outreach staff, research manager and dental students during DOOHS

Research Paperwork Responsibility	Outreach Supervisors	Outreach Nurses	Final Year Dental Students	Research Manager
Distribution of Patient Information Packs	x	✓/x	✓	x
Completion of Consent Forms	✓	✓	✓	x
Completion of Log-sheets	✓	✓	✓/x	✓
Collection of Participant Questionnaire	x	✓/x	✓	x
Site File Management	x	✓/x	x	✓
Audit of logs and paperwork	x	x	x	✓
Recording of breaches of protocol and adverse events	✓	✓	x	✓

Key: (x no involvement; ✓ fully responsible; ✓/x partial responsibility)

Table 7.2: Table displaying the outreach clinic research paperwork organisation by the outreach clinics during DOOHS

Site	Number of outreach chairs	Local responsibility for paperwork	Paperwork organisation
Aberdeen	6	Students & Staff	In cupboard off main clinic & under worktop.
Springfield	3	Dental nurse	In folder moved between surgeries.
Cupar	3	Staff	Desk space in staffroom.
Kings Cross	4	Dental nurse	Designated shelf in clinic.
Kirkcaldy	3	Staff	Designated desk in staff room.
Inverness	8	Students	In nurse's office on floor under desk.

The number of Patient Information Packs given to the clinics and the number distributed by each clinic was recorded, alongside the number of patients subsequently recruited to the study by each clinic (Table 7.3).

Research Objective 1 - Would Outreach clinics distribute patient information for a clinical study?

The clinics were given the packs which remained in the clinics until the termination of the recruitment phase (April 2011). At the end of the recruitment phase any remaining packs were taken back from each clinic and counted. The number of remaining packs was subtracted from the number originally given to the clinic. The remainder was the number of packs assumed distributed to outreach patients. The clinics were also required to complete a log-sheet recording pack distribution. Many clinics gave up completing these log sheets due to lack of time, the other paperwork required for the study was viewed of higher priority. Additionally, the students reported how many packs they had distributed to patients as part of the end of study questionnaire (discussed in Chapter 9). On the outreach clinics, the students were observed to be reluctant and hesitant to distribute information during the initial stages of the study. At some of the outreach clinics the staff were helpful in encouraging and reminding the students to *'just get on with it'* (outreach supervisor Kirkcaldy). The dental nurses were excellent research advocates at Kings Cross and Springfield outreach clinics, often handing out packs and chasing patients when the students forgot to distribute information. At these two clinics there was continuity of nursing support which was identified as a factor facilitating pack distribution: the nurses got to know the students well and could guess which students would not distribute packs. They also knew the patients well and could remember those who had already received envelopes. The nurses' relationship with outreach patients was very helpful to encourage research interest and participation.

Research finding:

- (i) Outreach clinics will distribute patient information for a clinical research study.

- (ii) Dental nurses are most proactive in facilitating this.
- (iii) Around 28% of packs distributed resulted in a participant for DOOHS.

Table 7.3: Patient information pack distribution and subsequent recruitment of participants by outreach clinic.

Outreach Clinic	Number of Patient Information Packs given to Outreach Clinic	Number of Packs Used (assumed distributed) by Outreach Clinic	Number of Participants Recruited	Percentage of pack assumed distributed resulting in recruitment
Aberdeen	200	124	32	25.8%
Springfield	125	71	24	33.8%
Cupar	125	89	20	22.5%
Kings Cross	125	125	41	32.8%
Kirkcaldy	125	116	43	37.1%
Inverness	200	53	5	9.4%
Total	900	578	165	28.5%

Research Objective 2 - Would outreach patients wish to participate in a clinical study during dental appointments?

The first participant was recruited to the Dental Outreach Oral Hygiene Study on the 28th January 2011.

A total of 165 participants over four health boards and six outreach centres enrolled in the study during the four months of recruitment, 28.5% of packs used by the clinics (and assumed to have been distributed to patients, resulted in participant recruitment for DOOHS and this information is outlined in table 7.3. The highest recruitment rates were at Kirkcaldy outreach clinic, where the outreach supervisor and nursing staff had a close relationship with patients. This clinic had many returning patients who had been attending the clinic for some time. Patients in Kirkcaldy openly discussed how grateful they were to the outreach clinic. This was

one clinic where the author had opportunity to carry out review appointments out-with student term time and speak to participants directly. The participants were all enthusiastic about their dental care and viewed the study as another aspect of this care. They were happy to return for review appointments with the researcher where no additional dental treatment would be provided.

Research finding:

- (i) Outreach patients wish to participate in a clinical study during dental appointments.

Research Objective 3 - Would dental students recruit participants to a clinical study?

The initial target for each dental student researcher was recruitment of 25 participants (as per power calculation). None of the dental students recruited this number. The highest number of participants recruited by a single student researcher was six. This was achieved by two dental students, one each from intervention and control groups, each recruited six participants. Remaining student researcher recruitment figures are outlined in Table 7.4. Lack of continuity of care proved to be a barrier to participant recruitment. As the students who distributed the patient information packs would not necessarily see the same patient again, there was reliance on an altruism with regards to participant recruitment. Some students were initially slow to hand out packs, yet benefitted from their enthusiastic colleagues' pack distribution. In hindsight, it may have been beneficial to have the packs posted to patients (which was not an option due to lack of funding for this study) or handed responsibility for pack distribution to the dental nurses at every outreach clinic.

Table 7.4: Behaviour of dental students with regards to number of participants recruited.

Number of Participants Recruited by a particular student	6	5	4	3	2	1	None
Number of intervention group recruiting this number of participants	1	2	6	4	9	7	5
Number of control group recruiting this number of participants	1	5	4	8	7	3	5

The intervention group recruited a total of **77** participants. The control group recruited a total of **88** participants.

Research finding:

- (i) Dental students will recruit participants to clinical studies in dental outreach.

Research Objective 4 - dental students could successfully consent participants to clinical studies in outreach.

There had been much discussion around the issue of consent for clinical research in dental outreach. The final consensus was that dental students could complete consent which would be overseen and countersigned by research trained staff and dental nurses. Consent forms were checked by the author during monitoring visits. Initially, there were some teething problems with a handful of participants ticking instead of initialling the consent forms as required by the protocol. This had not been picked up by staff overseeing the consent. This was quickly addressed for these cases, a new form was completed at the participant's next dental visit and a record made in the participant's dental notes. Out of 167 participants recruited, 165 had correctly completed consents and were included in the study. The remaining two participants did not re-attend for new consents and were therefore excluded from analysis.

Research finding:

- (i) Students can successfully consent participants for clinical studies in outreach.

Research objective 5 - Could dental students successfully record simple measures for a clinical study into oral hygiene delivery?

The measures chosen for DOOHS involved dental students recording plaque and bleeding charts. The system chosen was the O'Leary system, which although not particularly sensitive (being a dichotomous scoring method), was the system the students were familiar with from their teaching in Dundee Dental School. No students or outreach staff reported any difficulty with the charting. Clinical observations indicated that the students were confident in taking these measures. During monitoring visits the chart calculations were checked by the author. Occasionally, there was a discrepancy with missing teeth not having been completed, or reappearing on review charts (3 charts), and the occasional miscalculation (<10 charts). These discrepancies affected a very small number of charts and, during monitoring visits, were easily identified and corrected, before removing forms from the clinic. The DOOHS training film had demonstrated the correct recording and calculation of measures but had not emphasised the requirement for checking the number of teeth recorded on the chart matched the participant's dental chart in the notes. Adding in this extra student researcher check may have saved time at monitoring visits.

Research Finding

- (i) Dental students can successfully record simple measures such as plaque and bleeding charts, however they require assistance with checking calculations.
- (ii) It may be advisable for future studies in outreach to use a computerised recording system which automatically carries out calculations.

Research Objective 6 - Could dental students deliver a simple clinical study intervention in dental outreach clinics?

Students were observed during monitoring visits and dental outreach staff were questioned about the students' delivery of oral hygiene instruction. During monitoring visits the standard of instruction observed was considered very high and the interventional oral hygiene delivery could be identified from the control group. Dental outreach staff were happy with the quality of oral hygiene instruction delivered and praised the students on several occasions. Feedback from participant questionnaires was also favourable.

Research finding:

- (i) Dental students can deliver a simple clinical study intervention such as oral hygiene instruction in dental outreach clinics.

Research Objective 7 - Could baseline paperwork for a clinical study be successfully completed in dental outreach.

The completion of paperwork was the most unpopular component of DOOHS. At monitoring visits all paperwork was checked. Clinics varied with the amount of help they required with the paperwork. The busier clinics: Aberdeen and Inverness, required more help and assistance in completing the required participant log-sheets for the study. The CRF's were, in the main, correctly completed as were the consent forms. The research identification numbering system worked extremely well with no problems after the first couple of weeks once dental students remembered to keep a note of their researcher numbers with them. At the smaller clinics: Kirkcaldy, Springfield and Kings Cross, much pride was taken in the correct completion of the paperwork. These clinics were interested in their progress and there was a useful element of competition between the clinics. Dental staff and nurses at these smaller clinics asked questions during monitoring visits and were keen to learn from any mistakes in the paperwork. On average the checking of paperwork at these sites took only 20-30mins for the author compared to 3 hours at the larger clinics due to the

number of errors. The dental students were left to themselves to complete paperwork in the larger clinics due to the level of activity on the clinics. The lack of continuity or designated research areas at these clinics most likely contributed to the difficulties with the paperwork at the larger outreach clinics.

Research finding:

- (i) Baseline paperwork can be successfully completed in clinical research studies in outreach.
- (ii) Larger clinics require additional support from the research team, especially in the initial weeks with this.
- (iii) Research paperwork completion should be included in any training film.

Research Objective 8 - What level of support is required for clinical studies in outreach during recruitment phase?

The level of support given to the clinics during DOOHS was two sessions (7 hours) each fortnight per clinic for the first two months of the study and thereafter, as required, with additional monthly monitoring visits to each clinic. The main challenge in supporting the study was being on site when the students were actively recruiting participants. For the majority of the time in outreach, students were providing dental care and not involved in recruiting participants. Although assistance could be given to the dental students when each patient received study information with regards to discussing DOOHS, being on clinic for the recruitment stage was less predictable. Whole days were spent on outreach clinics where there were no patients attending who had previously received DOOHS information and could be recruited. It was difficult to predict how busy a session would be. After the initial weeks, dental nurses at Springfield and Kings Cross outreach clinics would try and rebook the potential participants in for appointments when the author would be on site to help with the recruitment visit if required. This worked much more efficiently, allowing real-life run through of paperwork completion and the main

points of consent. This possibly helped to ensure that paperwork was completed to a high standard at these two sites.

The level of support required for studies in outreach therefore cannot be measured in number of sessions, but rather how the support is organised. It was more productive to have several potential participants returning on a specific day and have a researcher on site at this time. Care would have to be taken to ensure that certain groups of students were not disadvantaged by this organisation and that each student group received an equal amount of support.

Research finding:

- (i) This particular study benefitted from the author being on site when the participants were initially recruited.
- (ii) Future studies in outreach should consider clinics having a list of dates in advance of when the research manager would be on site to facilitate research protocol paperwork. Once each clinic has benefitted from a whole day of research support, each clinic could then determine what further support they require.

7.1.4 Participant Baseline Demographics

The demographics of outreach patients participating in DOOHS were recorded using participant questionnaires. These questionnaires measured participants':

- sex,
- age,
- smoking habits,
- reported oral hygiene behaviours, and
- when participants last received dental treatment.

Clinical measurements were recorded by the dental students. These measured:

- plaque scores, and
- gingival bleeding scores.

The demographics at baseline are shown in Tables 7.5 and 7.6 and Figures 7.2 to 7.14. These demonstrate similar spread across the intervention and control groups at baseline.

Table 7.5: DOOHS group demographics for control and intervention groups with regards to male and female participants, and smoking habits.

Demographic	Control Group (88)	Intervention Group (77)
Number of Males	51	45
Number of Females	34	29
(Missing data)	(3)	(3)
Number of Smokers	30	28
Number of Non-Smokers	54	46
(Missing data)	(4)	(3)

Table 7.6: Range of ages of participants for control and intervention groups in DOOHS

Participant Group	Number of participants	Std. Deviation	Median age	Minimum age	Maximum age
Intervention	74	15.895	51	18	79
Control	85	16.140	50	21	79
(Missing ages)	6	-	-	-	-
Total	159	15.976	51	18	79

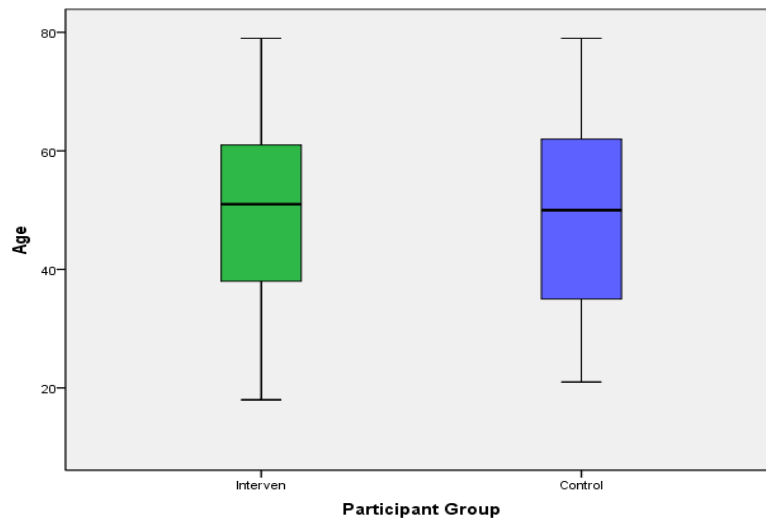


Figure 7.2: Box and whisker plot showing evenly matched age distributions for intervention and control groups with maximum and minimum ages as outliers.

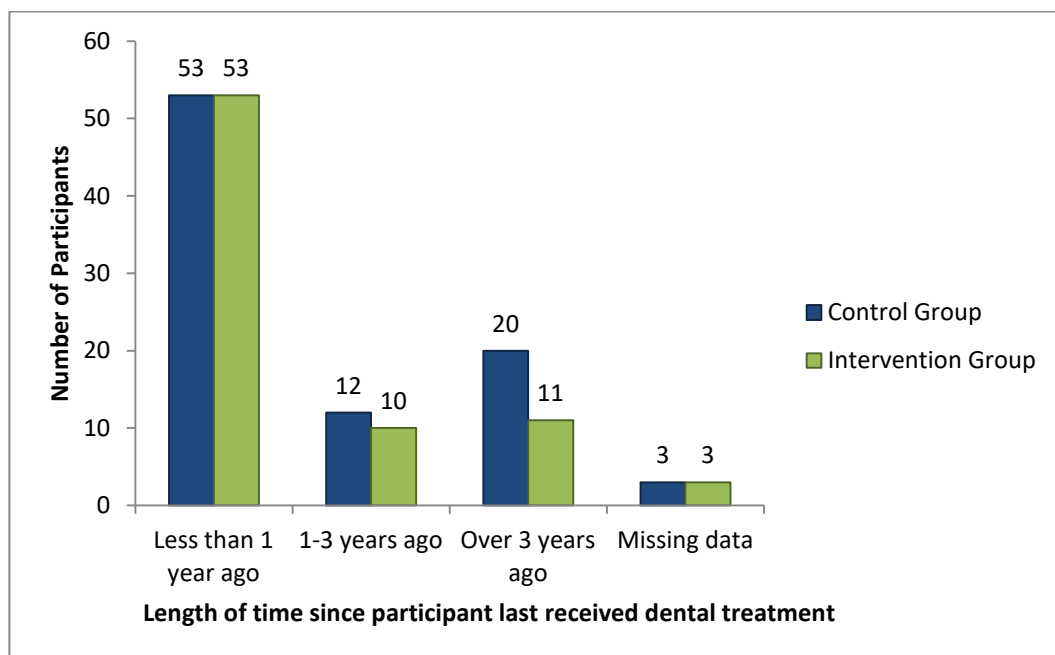


Figure 7.3: Bar chart demonstrating similarity between the groups for the last time participants received dental treatment before DOOHS.

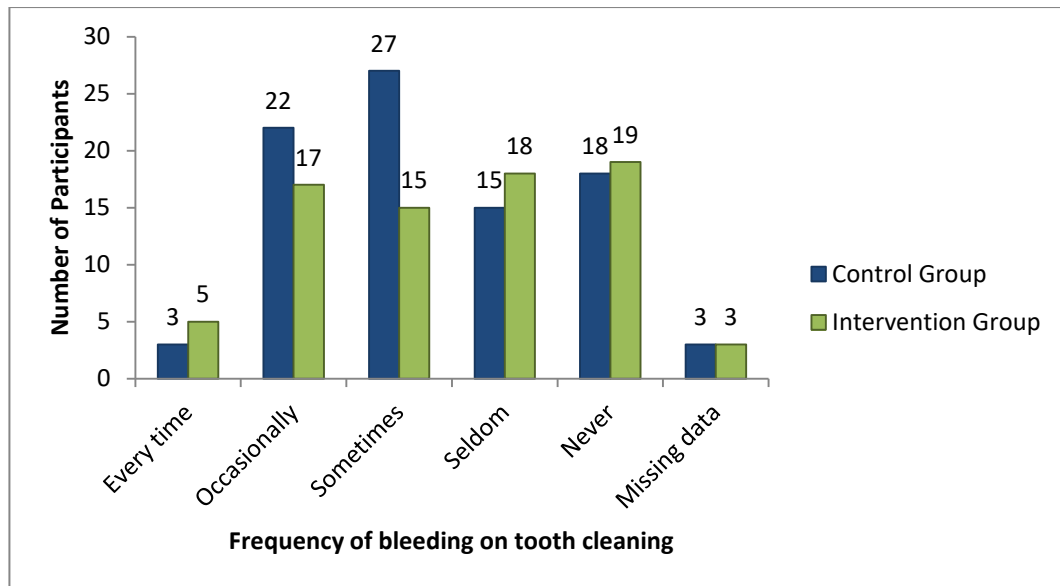


Figure 7.4: Bar chart demonstrating reported bleeding on tooth cleaning before DOOHS for control and intervention group. “Do your gums ever bleed when you clean your teeth?”

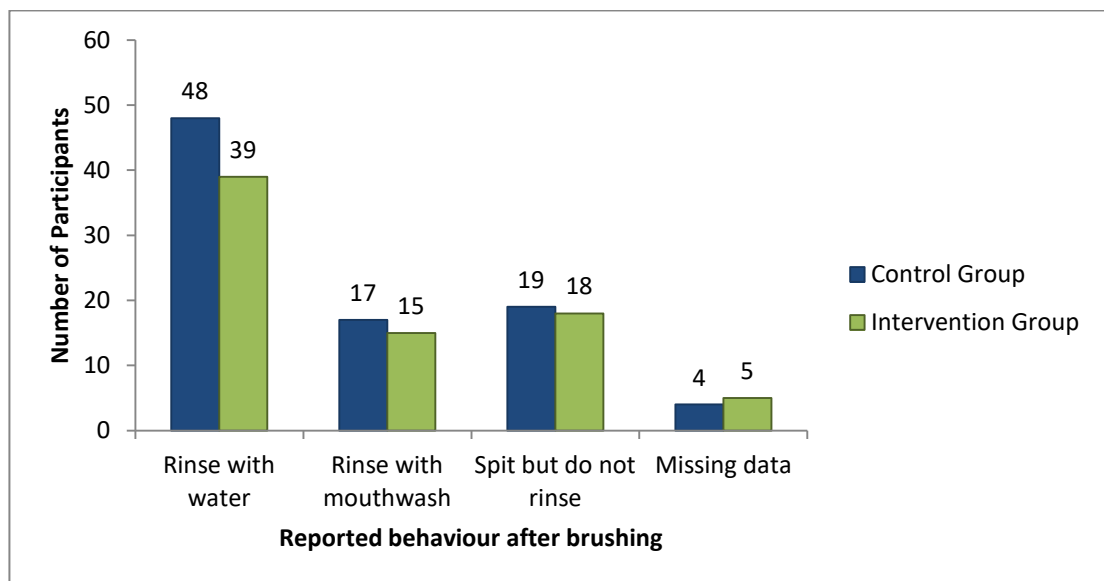


Figure 7.5: Bar chart demonstrating reported behaviour after brushing at baseline for control and intervention group. “After brushing do you usually...”

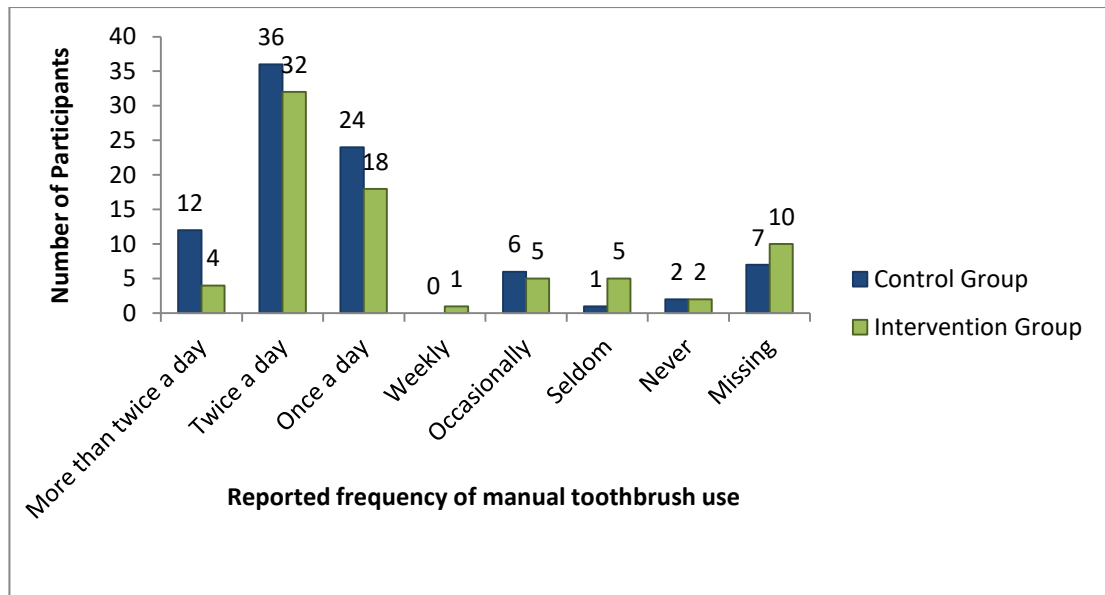


Figure 7.6: Bar chart demonstrating reported frequency of manual toothbrush use at baseline for control and intervention group.

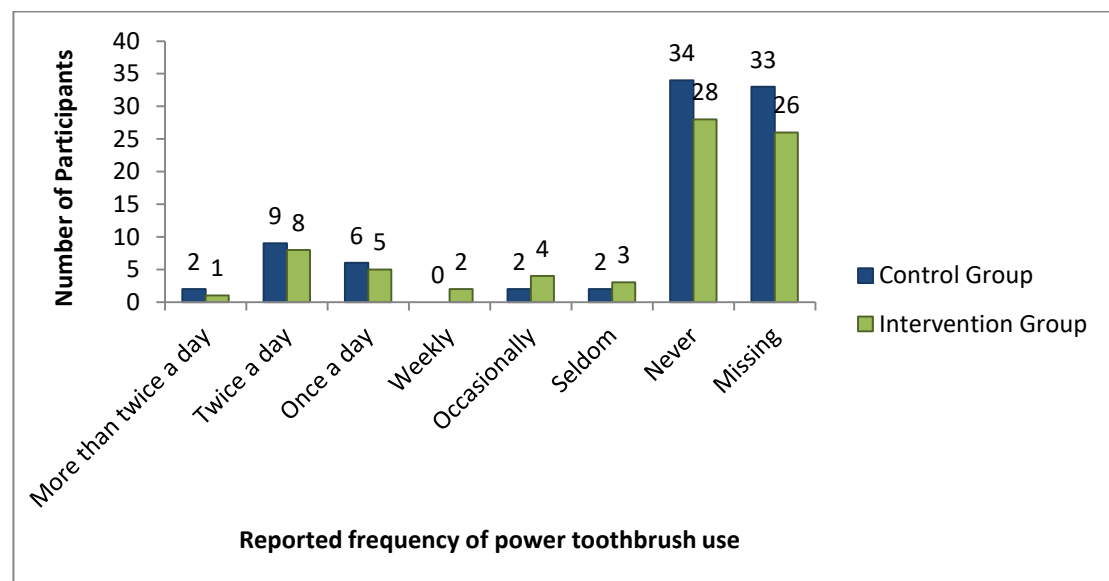


Figure 7.7: Bar chart demonstrating reported frequency of power toothbrush use at baseline for control and intervention group.

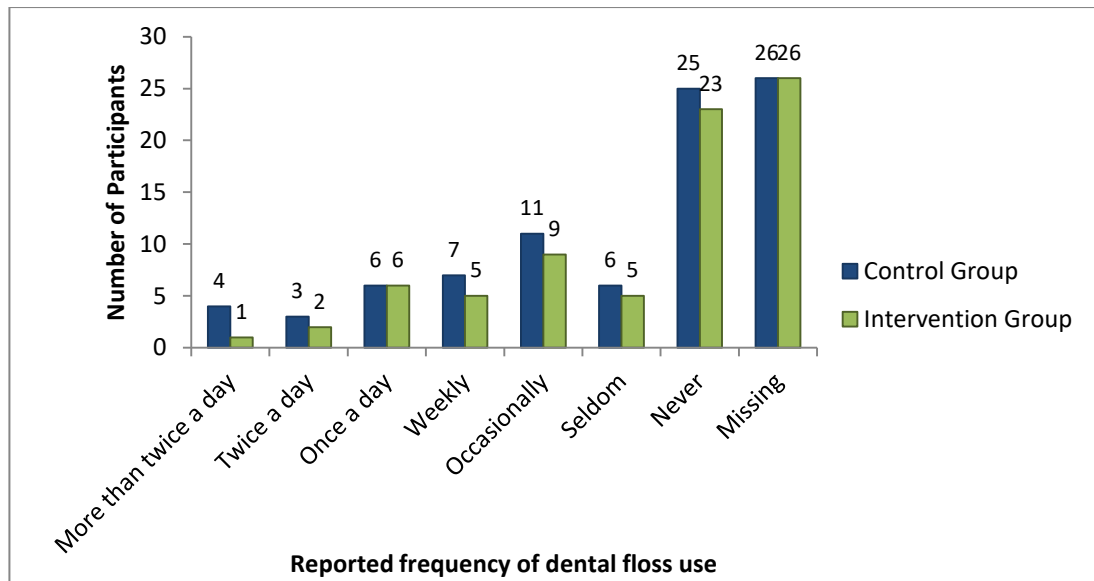


Figure 7.8: Bar chart demonstrating reported frequency of dental floss use at baseline for control and intervention group.

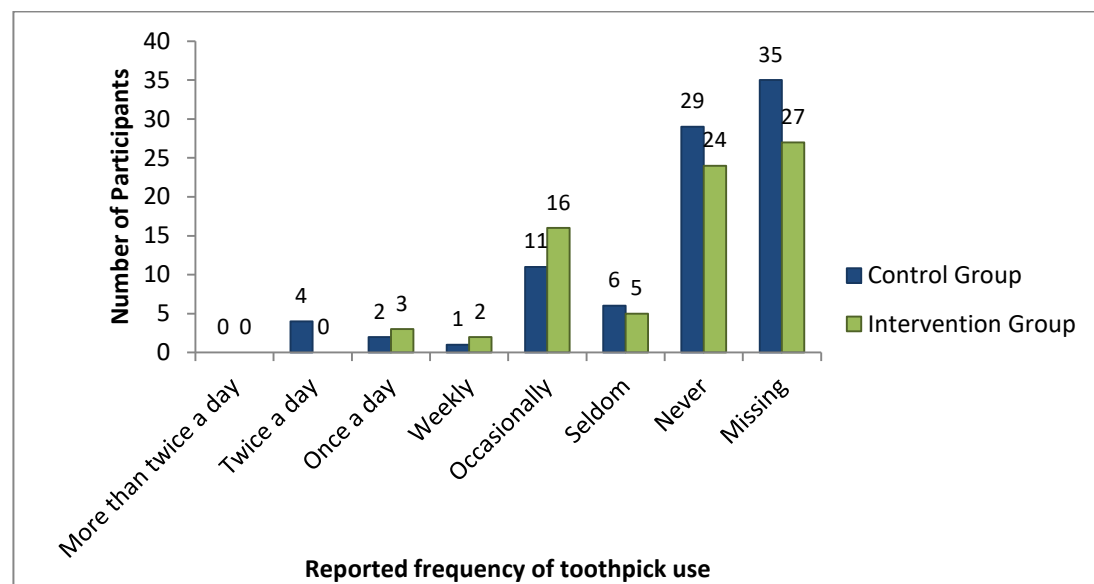


Figure 7.9: Bar chart demonstrating reported frequency of toothpick use at baseline for control and intervention group.

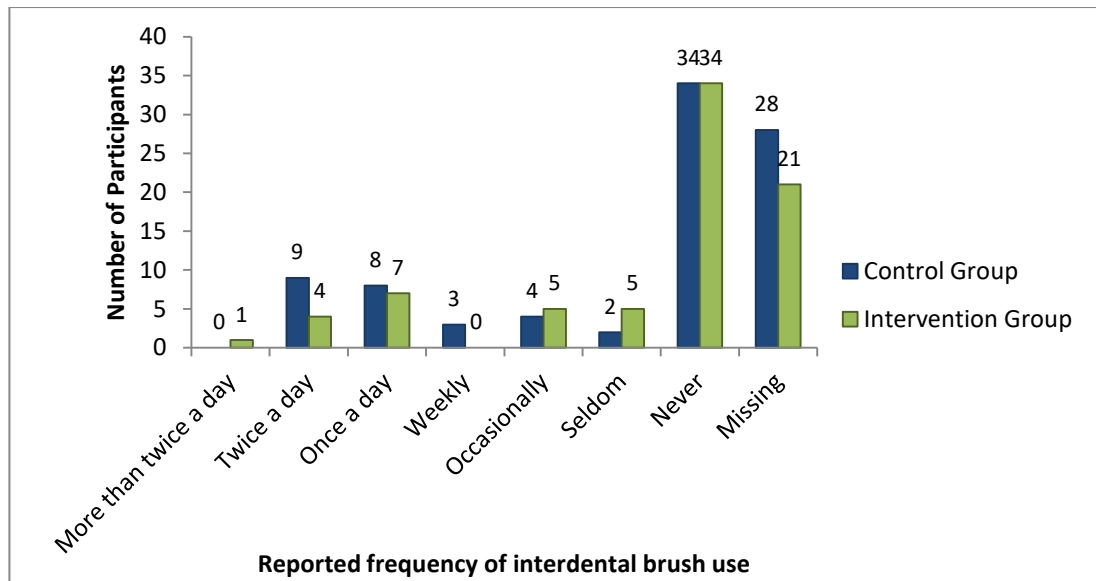


Figure 7.10: Bar chart demonstrating reported frequency of interdental brush use at baseline for control and intervention group.

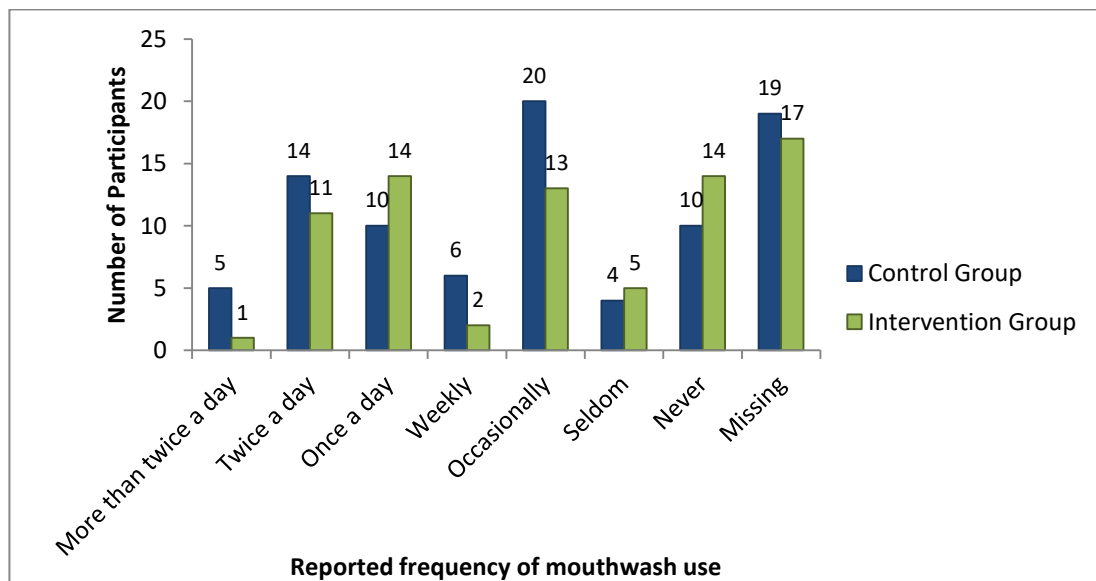


Figure 7.11: Bar chart demonstrating reported frequency of mouthwash use at baseline for control and intervention group.

The plaque and bleeding scores and numbers of natural teeth in the control and intervention groups at baseline are displayed in the box and whisker charts below.

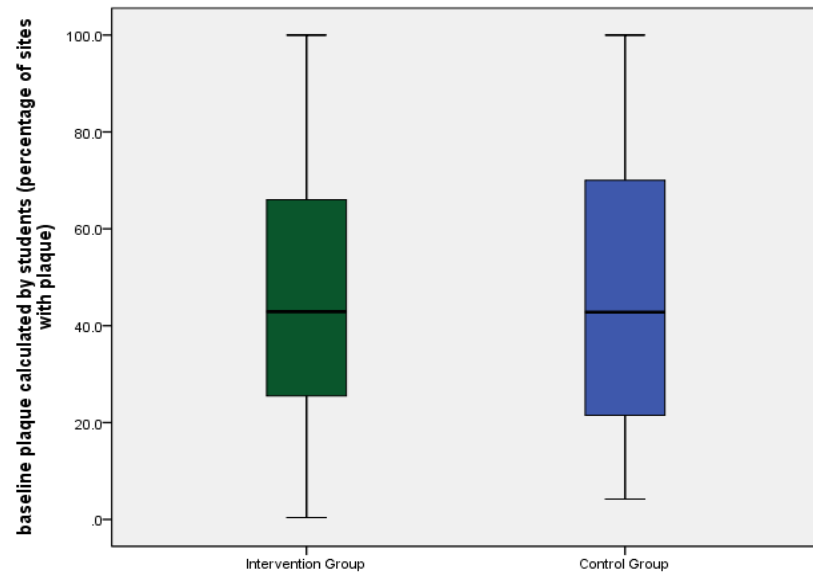


Figure 7.12: Box and whisker chart demonstrating similar plaque scores for control and intervention groups at baseline.

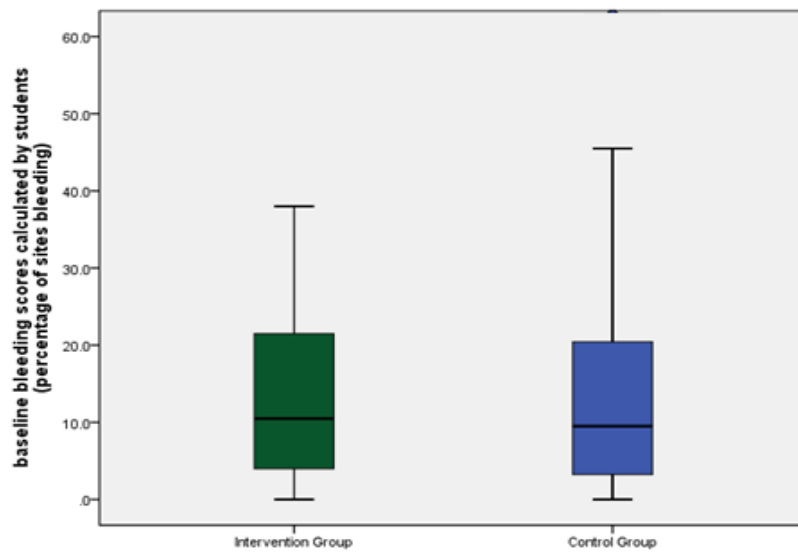


Figure 7.13: Box and whisker chart demonstrating similar bleeding scores for control and intervention groups at baseline.

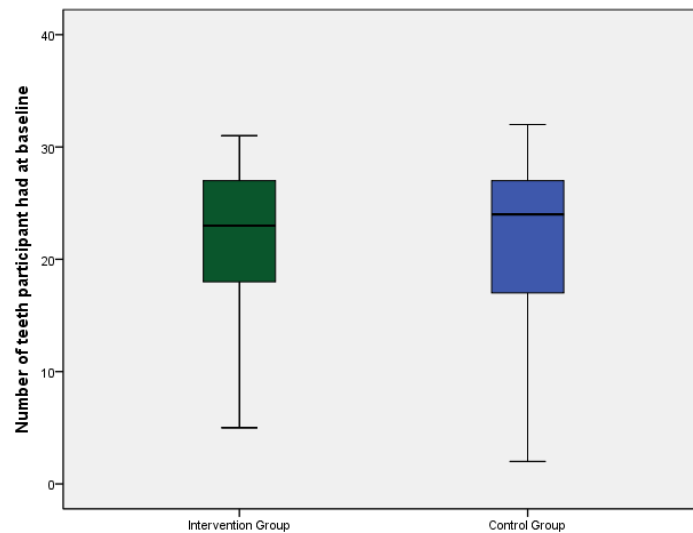


Figure 7.14: Box and whisker chart demonstrating higher mean number of natural teeth scores for control group compared to intervention group at baseline, but similar spread.

7.1.5 Recruitment of Participants Discussion

It was initially anticipated, during the planning stage, that the target of 25 participants per student would take under a month. This was estimated based on the number of patients passing through the outreach clinics. In reality, the recruitment of participants was much slower and although recruitment was continued for three months, DOOHS failed to recruit the numbers of participants hoped for.

The main reasons for the slow recruitment of participants were:

- initial overestimation of the numbers of patients receiving treatment on outreach clinics
- lack of enthusiasm for the study from dental students recruiting patients
- students and staff ‘just getting on with treatment’ and not considering research

The outreach clinics provide treatment for patients who have not previously received dental care for many years. Patients are treated by dental students who are relatively

inexperienced compared to general dental practitioners and are required to have their work checked at particular points during procedures. Treatment therefore takes much longer than it would in general dental practice and patients often return for a series of appointments to complete their treatment. This results in many repeat visits. These patients could have enrolled for DOOHS but their repeat attendance at the clinic over the recruitment month would have used appointments which could potentially have allowed new patient contacts to be made. This reduced potential recruitment to DOOHS. Overall, continued registered patient treatment would have reduced the number of potential participants each clinic could recruit. Dental nurses confirmed this on visits to clinics. It was apparent that many of the attending patients had already enrolled in DOOHS, however the actual recruitment numbers were low; the same patients were seen many times during that term.

Students were responsible for distributing packs to every potential participant they treated in outreach. However training had failed to generate enthusiasm towards DOOHS. This came across during participant information delivery where some students were observed informing patients: *“This is Dr. Richardson’s PhD, if you want to do it?”* - this was not the enthusiastic patient information delivery which had been hoped for.

Several students asked the consultant with responsibility for dental outreach whether they were required to collaborate with DOOHS as they did not see it as part of clinical dentistry. They were not happy that that collaboration was required for their final year. The number of packs distributed from the largest outreach clinic was disappointingly low with three-quarters of packs returned to the author. This clinic had the highest number of patient contacts and had been expected to recruit high numbers of participants, however the clinic had unforeseen challenges to DOOHS. At this clinic there was no particular member of staff taking responsibility for the study and the dental nurses were regularly rotated between the outreach and GDS services. The second largest outreach clinic also distributed a lower than expected number of patient information packs. This outreach clinic reported that staff were short of time to complete the DOOHS paperwork. This clinic had a high number of patient contacts and shorter lunch time (of 30 minutes) which perhaps reduced the

opportunity for catching up with items at the end of a session. The study materials were not immediately obvious or organised at either of these large outreach clinics and this would have been a barrier to students handing out packs.

The smaller outreach clinics performed better with pack distribution and participant recruitment relative to the number of chairs and patient contacts per day. Three of these clinics had members of staff who took on the responsibility of the study. The mind-set of the staff in these outreach clinics was to *'just get on with it'* and students were consistently reminded about the study. These staff took pride in distributing their packs and the number of participants they recruited. The organisation of study materials was better at these clinics. It would appear that the smaller sites placed a higher value on the study materials. Folders and logs were easily accessible and well organised (*Figure 7.1.6*) compared to the larger clinics where the study was viewed as more of an inconvenience. At two of the smaller outreach clinics the dental nurses took responsibility and were often seen distributing patient information and discussing the study with potential participants. The dental nurses took a very active role in DOOHS.



Figure 7.15: Photograph of DOOHS 'station' at Kirkcaldy outreach clinic: materials easily accessible to students, algorithm displayed on wall, and research materials easily accessible to dental students.

The recruitment phase of DOOHS relied, by design, on an element of altruism: the student who distributed the information about the study would most likely not see the patient at the next appointment for recruitment due to the lack of continuity between students and patients in outreach at the time. Therefore although some students distributed information about DOOHS to many patients, it was their colleagues who benefited in recruiting the patient. It had originally been anticipated that all students would distribute information and that the lack of continuity would not impact on the numbers recruited, however the disinterested students and lack of altruism reduced the numbers of patient information packs distributed.

Dental students were not always aware that their patients had received the study information. On observational visits to the clinics, potential participants were additionally seen to arrive with their baseline questionnaire already completed. However, this was then missed or ignored by the student, and it was not until they were reminded, on one occasion by the patient, that they were then prompted to carry out the baseline visit.

Dental emergencies or problems may have resulted in failure to recruit some participants. A patient presenting in pain would, as expected, have their pain relief prioritised over research. This conclusion has been deduced from the review data, where some reviews were omitted due to students and staff providing both emergency and sometimes usual dental care for participants in their review visit times. It would therefore be reasonable to conclude that a small number of potential participants may have been lost in this way. This could easily happen if a particular student did not wish to carry out the research or wished to carry out a particular item on the participant's treatment plan instead.

Some outreach staff reported difficulty finding time for study paperwork; this was discussed with staff during site visits. Smaller sites seemed to have a better grasp of the paperwork at the recruitment stage. It is worth noting that these smaller sites included dental nurses in their training session for the study at the very beginning, and the same dental nurses then took up the responsibility for DOOHS paperwork.

Site visits were initially spent helping with questions concerning the study and ensuring the students remembered to distribute participant information packs. Once participant recruitment was underway, visits were mostly spent tracking down paperwork, completing log sheets, correcting mistakes and checking CRF's those which had been completed. The Kodak R4 patient notes system utilised by outreach clinics was invaluable in allowing items such as charts to be checked for accuracy, matching to dental records where information was missing.

7.1.6 Recruitment of Participants - Conclusions

- Clinics who had included dental nurses in their initial training groups demonstrated more accurate paperwork completion at the recruitment phase of the study.
- Outreach clinics benefited from one member of staff, on-site, taking responsibility during this clinical study.
- Research materials needed to be easily accessible and identifiable to dental students, designated 'research areas' where all the materials were stored were helpful.
- Dental students required constant reminders to distribute study information and would benefit from some incentive to carry out clinical research.
- The lack of continuity in outreach may have slowed the recruitment phase down.
- Dental nurses were essential in assisting the students in recruiting participants.
- Outreach patients were happy to participate in DOOHS.
- A recruitment phase of three months was not sufficient to recruit the high number of participants initially preferred.
- Future studies in outreach would benefit from having research trained dental nurses at each outreach clinic with protected time to carry out the additional research paperwork duties.
- Outreach clinics can successfully recruit small numbers of participants to clinical studies.

7.2 DOOHS Review Visits

DOOHS review visits were carried out at three and six months to measure the retention of participants over this time, and the short and long term benefits of oral hygiene instruction delivered on the clinics. These review visits are now discussed.

7.2.1 Review Visit Methods

The first group of dental students graduated and so a second group of dental students were trained to carry out the review visits. These visits took place between May and November 2011.

DOOHS participants were recalled to the outreach clinics for three and six month review appointments to measure the short and long term effects of the enhanced oral hygiene instruction. The method of organising these recall appointments varied between clinics. DOOHS protocol recommended the recruiting dental student should arrange the three month review as well as any additional visits for routine dental care at the baseline visit. Many participants received their recall this way. However, the majority of participants who successfully returned for recall had had their visit timing monitored by nursing staff (Springfield and Kings Cross), or outreach staff (Kirkcaldy) who personally took responsibility for review appointments to be sent out. These outreach clinics developed their own lists to help with this. These lists had a record of each participant, the baseline visit time, and the times when the three and six month reviews would be due. Outreach staff or outreach dental nurses then checked each month which review visits were due and arranged for these participants to be contacted, usually by post. Kirkcaldy, who had the highest number of participant returns, additionally contacted the patients by telephone the day before their appointments, as is the protocol for all dental appointments at this clinic to reduce the number of failed appointments

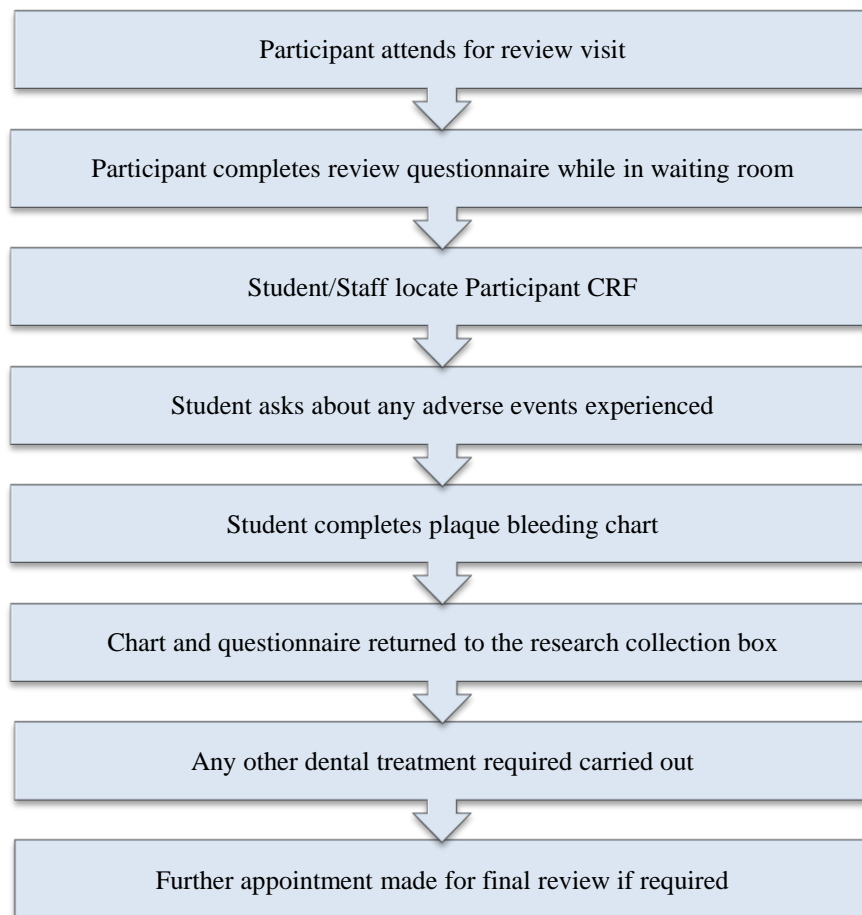


Figure 7.16: Methodology followed by the outreach clinics for participant reviews during DOOHS

Participants were generally examined within three weeks of their allocated three and six month review date, taken from the baseline visit. The exception was the final review visit. In order to maximise the number of returns, six month reviews were allowed to be up to six weeks late.

As the initial recruiting dental students were no longer attending outreach when the reviews were due, a successive group of final year students carried out these review visits. This benefited DOOHS by offering complete blinding to the participants' groups. Due to the student examinations and the student summer holidays, there were not always outreach clinics open during the times participants required reviews. If a participant could not be seen by dental students three weeks either side of their optimum review time, they were seen either by the author or by outreach staff within the required time limit for DOOHS.

The decision as to whether participants were seen by outreach staff or the author (in her position as research manager) was taken by the Senior Dental Officer for Outreach at each clinic. Inverness and Aberdeen organised their own review appointments, the preferred choice was that participants were seen by dental students unless staff were completing patient treatment during the summer, in which case they additionally carried out the review measurements. In NHS Fife and NHS Tayside, covering Kirkcaldy, Cupar, Springfield and Kings Cross outreach clinics, Senior Dental Officers sought permissions through their Clinical Dental Directors for the author to be given use of an outreach chair and nursing support to allow review of participants during student holidays. The author completed reviews in Kirkcaldy, Springfield and Kings Cross. These sessions were only possible thanks to the goodwill of the Clinical Dental Directors and the organisation of the outreach staff. This proved to be a very efficient method of quickly completing many reviews. The fifteen minute appointment slots additionally allowed provision of small items of emergency dental treatment if required, such as denture eases. Outreach participants were happy to attend these review appointments even if they were not receiving any additional dental care during the visit. Participants who did not attend review appointments within the time frame had their participant questionnaires posted out by the research team with a pre-paid envelope.

7.2.2 Review Visit Feasibility: Return Rate of Participants

Sixty seven dental students recruited 77 participants into the intervention group and 88 participants into the control group to give a total of 165 participants at baseline. The return rate of the review appointment data is complicated by the different ways participant data could be missing (plaque and bleeding scores, questionnaire or both). Participants who attended the outreach clinics for review all had their plaque and bleeding scores measured. The majority of these participants completed the questionnaire at that visit, and as such, both of the measures were taken (plaque, bleeding and reported oral health behaviours). Some of these participants however, did not have a questionnaire with the CRF when the author collected these from the clinics – these had most likely been forgotten at the appointment. These participants,

and those who did not attend an appointment for review had review questionnaires mailed to them with a prepaid return envelope organised by SDPBRN.

At the 3 month reviews 53 intervention participants and 52 control participants returned to the clinics for their measures to be recorded (total 105 participants at 3 months). At 3 months 60 intervention participant and 64 control questionnaires were received (total 124 questionnaires).

At the 6 month reviews the intervention group saw 42 participants return to have their plaque and bleeding scores recorded while the control group had 49 participants return for plaque and bleeding measurements. At 6 months 49 intervention and 55 control questionnaires were received. Thus, some patients returned questionnaires but did not attend review appointments.

The consort diagram of participants during DOOHS is outlined in figure 7.17.

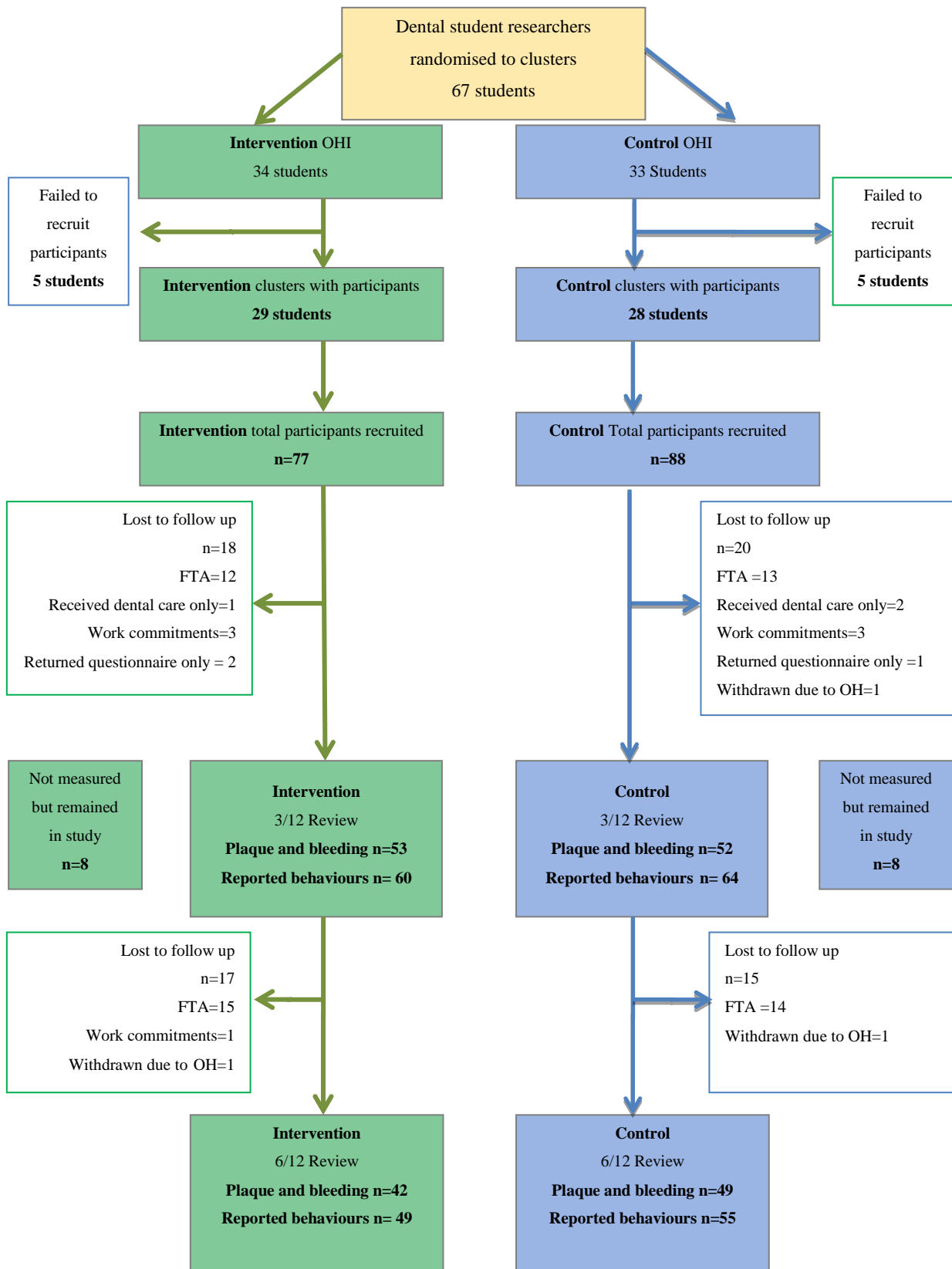


Figure 7.17 Consort diagram of patients during DOOHS

Reasons for loss to follow up were determined firstly from the research case report forms, and, additionally from dental notes. Participants lost to follow up are detailed in Table 7.7.

Table 7.7 Reasons why DOOHS participants were lost to follow up at three and six month reviews.

Reasons lost to follow up >	Failed to attend appointment	Dental treatment prioritised	Patient withdrew due to other commitments	Staff withdrew patient due to oral hygiene	Returned questionnaire only	Total
Intervention group						
Lost to follow up 3/12 appointment	12	1	3	0	2	18
Missed 3/12 but stayed in the study	5	2	0	0	1	8
Lost to follow up 6/12 appointment	15	0	1	1	0	17
Control group						
Lost to follow up 3/12 appointment	13	2	3	1	1	20
Missed 3/12 but stayed in the study	8	1	0	0	4	13
Lost to follow up 6/12 appointment	14	0	0	1	0	15

7.2.3 Demographics of Participants Attending Return Visits

The demographics at return visits are shown in Tables 7.8 and 7.9 and in Figures 7.17 to 7.19.

Table 7.8: DOOHS group demographics for control and intervention groups with regards to smoking habits at three and six month return.

Demographic	Control Group (Baseline =88)		Intervention Group (Baseline = 77)	
	3 months	6 months	3 months	6 months
Returns	63	54	58	46
Number of Smokers	26	18	22	15
Number of Non-Smokers	37	36	36	31
(Missing data)	(25)	(34)	(19)	(31)

Table 7.9: Range of ages of participants for control and intervention groups in DOOHS at three and six month return

Participant Group	Number of valid participant ages	Std. Deviation	Median age	Minimum age	Maximum age
Intervention 3 months	57 (20 missing)	16.28	53	18	79
Control 3 months	61 (27 missing)	14.68	53	24	79
Total	118 (47 missing)				

Participant Group	Number of valid participant ages	Std. Deviation	Median age	Minimum age	Maximum age
Intervention 6 months	44 (33 missing)	15.58	55	19	79
Control 6 months	52 (36 missing)	15.66	57	24	79
Total	96 (69 missing)				

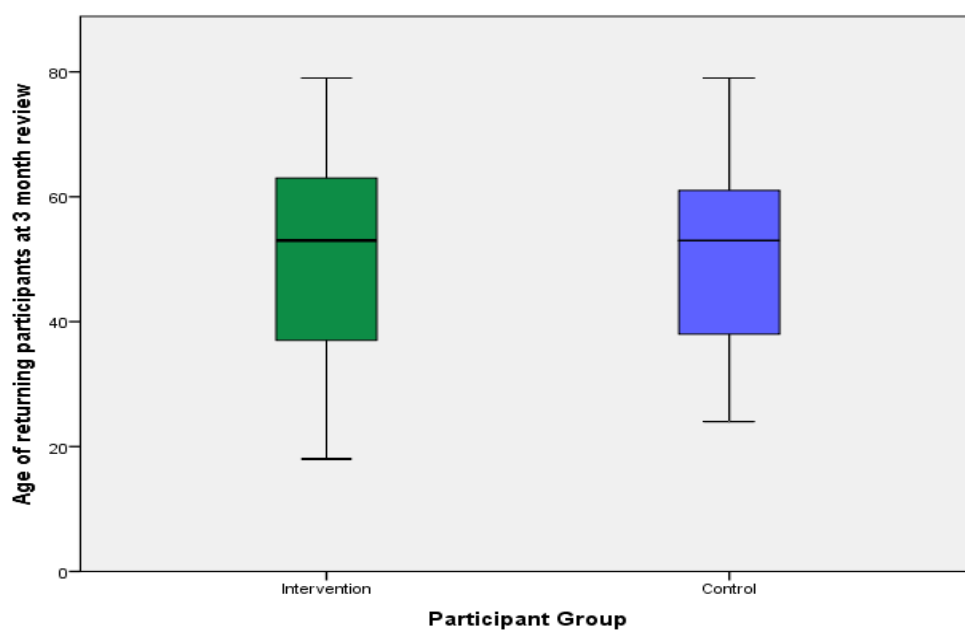
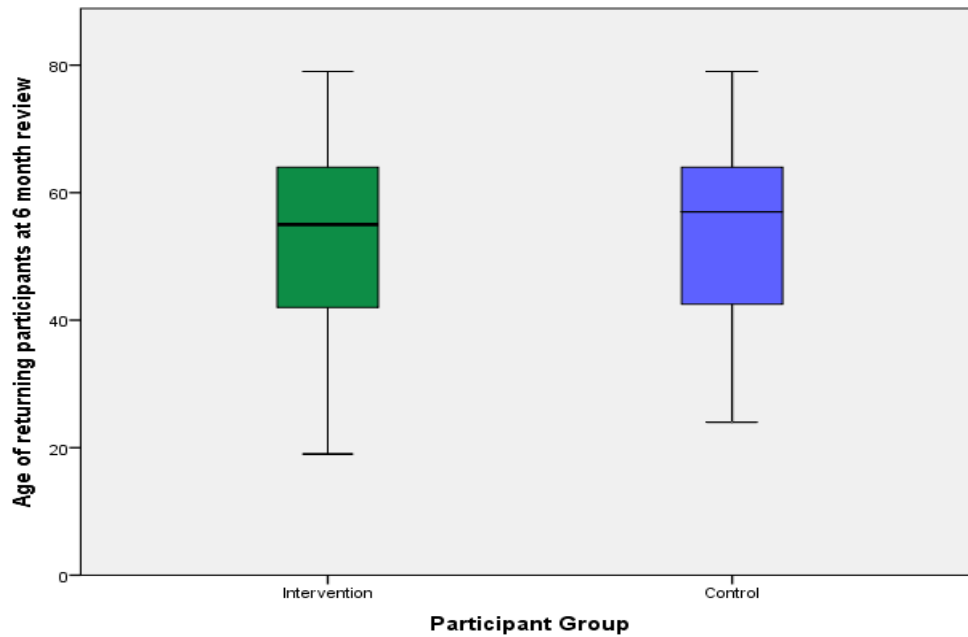


Figure 7.18 Box and Whisker plot showing age distributions for intervention and control groups with maximum and minimum ages as outliers at three month review



7.19 *Box and Whisker plot showing age distributions for intervention and control groups with maximum and minimum ages as outliers at three month review*

7.2.4 Review Visit Feasibility Discussion

The most common reason participants were lost to follow up was due to their failure to attend review appointments (FTA). This involved a total 67 participants during the study. There was no additional increase above usual FTA rates experienced by the clinics during this study. The FTA levels in outreach remained constant and it is therefore unlikely that participants were failing to attend due to the study, rather they were just patients who fail to attend appointments. Staff at three of the outreach clinics (Kings Cross, Kirkcaldy and Springfield) were very proactive in pursuing patients failing to attend, sending out additional appointments. These clinics saw higher return rates of participants. A small number of participants withdrew from the study due to work commitments.

In addition, there were participants who had their dental treatment prioritised over the study measurements when they attended for review. For example, this could be due to the patient presenting with dental pain. Three patients were lost from the study due to outreach staff being unhappy with their plaque levels and intervening

with further oral hygiene instruction. When these participants' plaque measurements were examined against their baseline levels, there was no increase in the level of plaque present compared with the baseline measurements. Twenty-one participants missed the three month review but subsequently returned at the six month review. These participants remained in the study and were sent out questionnaires by the research team.

7.2.5 Management of Loss to Follow Up

Where possible, participants who failed an appointment were sent another within two weeks. If an appointment was cancelled, measures taken to re-book the appointment within the month were considered acceptable. After a second failed appointment participants could be sent one further appointment at the discretion of the outreach supervisor. If a patient could not attend the outreach clinic, questionnaires were posted to the participants by the research team. Postal questionnaires had a 19% return rate.

7.2.6 Participants Remaining in the Study

The participants remaining in the study had a similar demographic to those at baseline. The range of ages across both control and intervention groups at baseline, three and six months changed very little. There was no particular drop of specific cohorts i.e. smokers, young patients, particular gender etc.

DOOHS had 64% of participants return for clinical (plaque and bleeding) measures at three months and 75% of questionnaire returns at three months. At six months this dropped to 55% of the original number of participants returning for clinical measures and 63% of questionnaire returns.

The three clinics with well organised research paperwork and staff ownership saw the highest retention rates. Future studies in outreach may improve retention of participants by:

- Having one trained dental nurse or outreach supervisor taking ownership of the study
- Organising simple logs at baseline detailing the month the participant is due review
- Arrange patient telephone reminders the day before the clinical research appointment

7.2.7 Review Visit Feasibility Conclusions

- Outreach clinics where a research trained dental nurse or member of teaching staff organised the return appointments had higher return rates of participants.
- Outreach participants are happy to return for appointments out-with the student term times.
- Clinical dental Directors will give permission for clinical researchers to review outreach participants if required and allow clinical space for this out with the student term.
- Outreach clinics would benefit from help with organising review appointments for participants, and with mailing out questionnaires.
- Dental students can carry out simple review visits alongside usual dental care for outreach participants if required.

The Results from DOOHS follow in Chapter 8.

Chapter 8: DOOHS Results, Discussion and Conclusion

This chapter discusses the Dental Outreach Oral Hygiene Study (DOOHS) which was implemented to test the feasibility of clinical research in dental outreach clinics. The Study objectives are reiterated in section 8.1, and a brief resume of the methodology is included in section 8.2.1. The methodology of analysis is outlined before the results in each section. This chapter investigates:

- Differences between control and intervention groups at baseline (section 8.3.1)
- Changes to reported oral health behaviours (sections 8.3.2 and 8.3.3)
- Plaque and bleeding results (section 8.4)

Information is provided regarding the analysis of the patient questionnaire, taking into consideration the theory of planned behaviour model. There is an evaluation of the impact of DOOHS on the clinical activity of dental students during the academic years involved (section 8.5) and conclusions with regard to DOOHS are noted in section 8.6.

8.1 Objectives of the Dental Outreach Oral Hygiene Study

The Dental Outreach Oral Hygiene Study had two objectives:

- i) To assess the effectiveness of oral hygiene instruction delivery on the periodontal health of dental outreach patients in the short term (three months) and long term (six months). Periodontal health was defined as lack of gingival bleeding on probing.
- ii) To assess changes in reported oral hygiene behaviours after each method of oral hygiene delivery in the short term (three months) and long term (six months).

These objectives tested the following null hypotheses:

- i) H_0 - Delivery of oral hygiene instruction, using a psychological framework and with the inclusion of biomarker information, results in no improvement to gingival bleeding when compared to standard oral hygiene instruction delivered within outreach clinics in the short (three months) or long-term (six months).
- ii) H_0 - Delivery of oral hygiene instruction, using a psychological framework and with the inclusion of biomarker information, results in no increase in reported oral hygiene behaviours, when compared to the standard oral hygiene instruction delivered within outreach clinics in the short (three months) or long-term (six months).

8.2 Methodology

8.2.1 Baseline Methodology

Participants were recruited between January and April 2011 by the final year students during their dental outreach attachments, as previously detailed in Chapter 7. The recruiting visit followed the study protocol outlined in Chapter 5. Prior to the recruiting visit outreach patients had received information about DOOHS and the participant questionnaire to take away, complete and bring back. At the recruiting visit, the final year dental students discussed the study and answered any questions outreach patients had regarding their participation. The eligibility of each potential participant was verified and the participant was then consented for DOOHS. This consent process was overseen by outreach staff.

After the patient had been consented, the student researcher allocated a six figure participant ID, consisting of a) the student researcher number, b) the site of recruitment code and c) the number of the participant recruited by that student. The baseline questionnaire was next collected from the participant, or, if this had been forgotten, the patient was left to complete this in the dental chair before the student returned to complete plaque and bleeding measures.

The plaque and gingival bleeding scores were recorded on the CRF which was pre-printed with blank O'Leary charts for each visit. The dental student then delivered oral hygiene instruction as per their group allocation. Once oral hygiene instruction had been completed the research component of the visit was considered complete and participant could go on to have dental treatment carried out as planned where outreach staff determined that there was time to do this. The review visit was booked for three months' time, together with any further visits for dental care. After the patient left the surgery, any remaining paperwork such as study log sheets were completed, by outreach staff and/or students depending on the outreach clinic set up.

The three month review visit was organised by each clinic. Some clinics set up this appointment with the participants immediately after the recruitment visit. Three of the outreach clinics had nursing or outreach staff who had organised their own log sheets for the study in order that they were aware of participants who were due for review each month and sent out appointments. At the six month review stage the majority of the outreach clinics had adopted this method of recalling their participants. The review visits were carried out by the 2011-2012 final year dental student group.

At the review appointment the student researchers completed the participant's CRF with the three or six-month plaque and bleeding scores and collected the participant review questionnaire (appendix 17). As the participants had previously been consented, these students had more time to complete any other dental treatment that was planned at the same appointment than the recruiting student group. Participants who missed their review and did not attend the clinic for rebooked appointments (the number of rebooked research appointments was left to the discretion of staff on each clinic) were posted a questionnaire by the research team with a pre-paid return envelope.

8.2.2 DOOHS Participant Questionnaire on Reported Oral Hygiene Behaviours: Background

The participant questionnaire was adapted from a previously-used questionnaire from the 2004 VDP study by Clarkson, which investigated changes with regard to oral hygiene behaviour. The Dental Outreach Oral Hygiene Study Participant Questionnaires additionally recorded patient demographics at baseline and participants' experiences during the clinical research study on the review visits. Smoking habits were recorded at each visit as this could change from visit to visit and may be expected to influence the recorded amount of gingival bleeding on probing. Patient demographics (age, sex, smoking habits and dental attendance) have been discussed in Chapter 7. The results relating to participants' experiences of participating in DOOHS are discussed in Chapter 9 as these do not form part of the DOOHS results but rather part of their post study views on clinical research in dental outreach. This section focuses on the outcomes of the clinical study: the reported oral hygiene behaviours of outreach participants and the plaque and bleeding measurements. It should be noted that the numbering of questions in the baseline questionnaire and the review questionnaire differed, and as such question numbers were aligned to the review question numbers for the purpose of analysis. The numbering of questions will therefore differ in the appendices.

The participant's questionnaire overall measured the intention of the participant to carry out oral hygiene behaviours. This followed Icek Ajzen's Theory of Planned Behaviour (Ajzen 2006). Ajzen explained that whether an individual carries out a health behaviour, such as tooth cleaning, is governed by their intention to carry out that behaviour which is constructed from their attitude towards the behaviour, their self-efficacy (perceived behavioural control) and their subjective norm. The constructs are identified in figure 8.1.

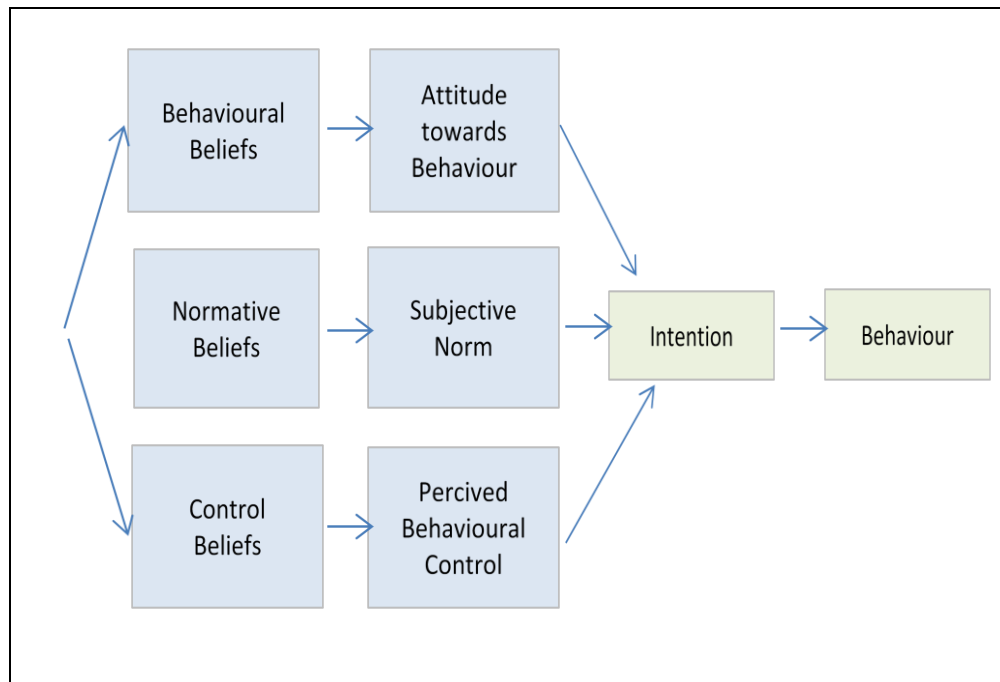


Figure 8.1 Ajzen's theory of planned behaviour

The particular questions in the participant's questionnaire (Appendix 17) which measure these constructs are now detailed:

Table 8.1: Questionnaire constructs linking to the theory of planned behaviour

Construct measured	No.	Question	Responses
Reported oral health behaviour	Q3	Do your gums ever bleed when you clean your teeth?	'every time', 'occasionally', 'sometimes', 'seldom', 'never'
	Q4	How long do you spend brushing your teeth?	'<30s', '30s-1min', '1min but under 2mins', '2mins', '>2 minutes'
	Q5	After brushing do you rinse out?	'rinse with water', 'rinse with mouthwash', 'rinse with water and mouthwash' or 'spit but do not rinse'

Construct measured	No.	Question	Responses
Reported oral health behaviour	Q6a	How often do you use a manual toothbrush?	'more than twice a day', 'twice a day', 'once a day', 'weekly', 'occasionally', 'seldom' 'never'
	Q6b	How often do you use an electric toothbrush?	
	Q6c	How often do you floss?	
	Q6d	How often do you use toothpicks?	
	Q6e	How often do you use brushes between your teeth?	
	Q6f	How often do you use mouthwash?	
Participant self-efficacy (perceived behavioural control)	Q7a	How confident are you that you can follow dental student advice about cleaning your teeth?	'not at all confident' to 'extremely confident'
	Q7b	How confident are you that you can clean your teeth so they can't be any cleaner?	
	Q7c	How confident are you that you can clean your teeth as often as you should?	
	Q7d	How confident are you that you can clean your teeth for as long as you should?	
	Q7e	How confident are you that you can clean your teeth the way that you should?	
Control belief	Q8a	I always find it easy to follow advice from the students about cleaning my teeth	'strongly agree' to 'strongly disagree'
	Q8b	I would always like to clean my teeth until they can't get any cleaner, but I don't think it's possible for me to do so	

Construct measured	No.	Question	Responses
Control belief	Q8c	I would like to clean my teeth as often as I should, but I don't think it's possible for me to do so	
	Q8d	I would like to clean my teeth for as long as I should, but I don't think it's possible for me to do so	
	Q8e	I would like to clean my teeth the way should, but I don't think it's possible for me to do so	
Subjective norm: Participant attitude towards tooth cleaning	Q9a	Cleaning my teeth is a good thing to do	<i>strongly agree</i> ’ to <i>‘strongly disagree</i> ’
Behavioural belief: Participant attitude towards tooth cleaning	Q9b	Cleaning my teeth is a boring thing to do	<i>strongly agree</i> ’ to <i>‘strongly disagree</i> ’
Outcome evaluation Participant attitude towards tooth cleaning	Q9c	Cleaning my teeth makes my mouth feel good	<i>strongly agree</i> ’ to <i>‘strongly disagree</i> ’
	Q9d	The more I clean my teeth the less decay I will get	
	Q9e	The more I clean my teeth the less gum disease I will get	
	Q9f	The longer I clean my teeth the less decay I will get	
	Q9g	The longer I clean my teeth the less gum disease I will get	
	Q9h	The longer I clean my teeth the less my gums will bleed	
	Q9i	The more I clean my teeth the less my gums will bleed	

Construct measured	No.	Question	Responses
Normative belief:	Q10	I think the dental students want me to	<i>agree</i> to <i>strongly</i>
subjective norm	a	clean my teeth differently from how I now clean them	<i>disagree</i>
Motivation to comply:	Q10	I don't care how the dental students	<i>agree</i> to <i>strongly</i>
subjective norm	b	think I should clean my teeth	<i>disagree</i>

The remaining questions aimed to gain insight into how the outreach participant viewed their time spent in the dental chair and the relative importance they attached to prevention.

Table 8.2: Other questions included to capture participant views

Q11a	It is important that the students take time with me
Q11b	It is important that I get my fillings done before anything else
Q11c	It is important that I get my gums treated before anything else
Q11d	It is important that my appointments are as short as possible
Q11e	It is important that the students get lots done so I don't have to come back as many times
Q11f	It is important that I receive preventive advice before anything else
Q11g	It is important that I have my usual treatment carried out as well as research at the appointment
<i>Likert: 'not at all important' to 'extremely important'</i>	

8.3 Participant Questionnaire Analysis of Results

The Dental Outreach Oral Hygiene Study design was a randomised controlled cluster trial with target recruitment of 25 participants per dental student researcher. This target recruitment number proved to be over ambitious to reach in dental outreach with six participants being the maximum number recruited by any student during recruitment stage. The majority of students recruited far fewer participants. It was not possible to fully analyse the results as a cluster trial due to low numbers recruited. The analyses were therefore carried out taking the participants simply as two groups: Intervention and Control. This made the assumption that the number of

students recruiting participants in each group would balance any differences in their delivery of oral hygiene instruction. The participant numbers recruited by individual students were very similar between the two groups therefore it was considered reasonable to carry out basic analysis in this way.

As Likert scales yield ordinal data (Field 2009), the participant questionnaires were analysed using non-parametric tests for the control and intervention groups taken over the three visits (baseline, three-months and six-months). Bonferoni's correction (Sedgewick 2014) was applied as required across the three timescales.

8.3.1 Control and Intervention Groups at Baseline

The baseline data from the control and intervention groups was assessed blind (group 1 and group 2) assessing for any statistical difference between the two groups at baseline. This was later decoded. At baseline we would expect there to be no significant differences between the two groups. Therefore, any significant differences identified from the results at three and six months could be assumed to be due to the intervention or control oral hygiene instruction delivery.

Table: 8.3: DOOHS demographics, sex of participants at baseline

	Male (%)	Female (%)	Missing (%)	Total
Intervention	45 (58.4)	29 (37.7)	3 (3.9)	77
Control	51 (58.0)	34 (38.6)	3 (3.4)	88

Table: 8.4: DOOHS demographics, ages of participants at baseline

	Number valid	Minimum	Maximum	Mean	Std Deviation
Intervention	74	18	79	49.31	15.089
Control	85	21	79	49.47	16.140

Table: 8.5: DOOHS demographics, number of smokers at baseline

	Smokers (%)	Non-smokers (%)	Missing (%)	Total
Intervention	28 (36.4)	46 (59.7)	3 (3.9)	77
Control	31 (35.2)	54 (61.4)	3 (3.4)	88

At baseline the two groups showed no statistical difference in smoking habits, age or sex of participants.

The oral health behaviours also showed no statistical difference between the two groups at baseline (as illustrated in table 8.6).

H₀, there is no difference between the control and intervention groups question responses at baseline.

Independent samples Mann-Whitney U tests were carried out and considered significant at a level of 0.05 on the remaining questionnaire questions. (At baseline we expect the null hypothesis to be upheld).

Table: 8.6: DOOHS results Independent Samples Mann-Whitney U Test for baseline demographics

Null Hypothesis	Independent Samples Mann-Whitney U Test Significance
The distribution of : When did you last receive dental treatment is the same across the categories of Intervention and Control group at baseline	0.177
The distribution of : Do your gums ever bleed when you clean your teeth is the same across the categories of Intervention and Control group at baseline	0.493
The distribution of : How long do you spend brushing your teeth is the same across the categories of Intervention and Control group at baseline	0.171

Null Hypothesis	Independent Samples Mann-Whitney U Test Significance
The distribution of : After brushing do you rinse out is the same across the categories of Intervention and Control group at baseline	0.476
The distribution of : How often do you use a manual toothbrush is the same across the categories of Intervention and Control group at baseline	0.150
The distribution of : How often do you use an electric toothbrush is the same across the categories of Intervention and Control group at baseline	0.725
The distribution of : How often do you floss is the same across the categories of Intervention and Control group at baseline	0.497
The distribution of : How often do you use toothpicks is the same across the categories of Intervention and Control group at baseline	0.625
The distribution of : How often do you use brushes between your teeth is the same across the categories of Intervention and Control group at baseline	0.435
The distribution of : How often do you use mouthwash, is the same across the categories of Intervention and Control group at baseline	0.267
The distribution of : How confident are you that you can follow dental student advice about cleaning your teeth, is the same across the categories of Intervention and Control group at baseline	0.278
The distribution of : How confident are you that you can clean your teeth so they can't be any cleaner, is the same across the categories of Intervention and Control group at baseline	0.743
The distribution of : How confident are you that you can clean your teeth as often as you should, is the same across the categories of Intervention and Control group at baseline	0.464

Null Hypothesis	Independent Samples Mann-Whitney U Test Significance
The distribution of : How confident are you that you can clean your teeth for as long as you should, is the same across the categories of Intervention and Control group at baseline	0.461
The distribution of : How confident are you that you can clean your teeth the way that you should, is the same across the categories of Intervention and Control group at baseline	0.611
The distribution of : I always find it easy to follow advice from the students about cleaning my teeth, is the same across the categories of Intervention and Control group at baseline	0.036*
The distribution of : I would always like to clean my teeth so they can't get any cleaner but I don't think it is possible for me to do so, is the same across the categories of Intervention and Control group at baseline	0.240
The distribution of : I would like to clean my teeth as often as I should but I don't think it is possible for me to do so, is the same across the categories of Intervention and Control group at baseline	0.443
The distribution of : I would like to clean my teeth for as long as I should but I don't think it is possible for me to do so, is the same across the categories of Intervention and Control group at baseline	0.632
The distribution of : I would like to clean my teeth the way that I should but I don't think it is possible for me to do so, is the same across the categories of Intervention and Control group at baseline	0.612
The distribution of : Cleaning my teeth is a boring thing to do, is the same across the categories of Intervention and Control group at baseline	0.234
The distribution of : Cleaning my teeth makes my mouth feel good, is the same across the categories of Intervention and Control group at baseline	0.318

Null Hypothesis	Independent Samples Mann-Whitney U Test Significance
The distribution of : Cleaning my teeth is a good thing to do, is the same across the categories of Intervention and Control group at baseline	0.330
The distribution of : The more I clean my teeth the less decay I will get, is the same across the categories of Intervention and Control group at baseline	0.369
The distribution of : The more I clean my teeth the less gum disease I will get, is the same across the categories of Intervention and Control group at baseline	0.287
The distribution of : The longer I clean my teeth the less decay I will get, is the same across the categories of Intervention and Control group at baseline	0.379
The distribution of : The longer I clean my teeth the less gum disease I will get, is the same across the categories of Intervention and Control group at baseline	0.146
The distribution of : The longer I clean my teeth the less my gums will bleed, is the same across the categories of Intervention and Control group at baseline	0.240
The distribution of : I think the dental students want me to clean my teeth differently from how I now clean them, is the same across the categories of Intervention and Control group at baseline	0.779
The distribution of : I don't care how the dental students think I should clean my teeth, is the same across the categories of Intervention and Control group at baseline	0.650
The distribution of : It is important that the students take time with me, is the same across the categories of Intervention and Control group at baseline	0.666

*Significance 0.05, Null hypothesis rejected

At baseline the 36 of the 37 question responses tested upheld the null hypothesis that there was no difference between the two groups at baseline. The one question which rejected the null hypothesis '*I always find it easy to follow advice from the students about cleaning my teeth*' was found to be significant at 0.036. This is only marginally below the 0.05 significance level. With 37 questions included in the

questionnaire it is probable that this result is a chance finding. The analysis results are displayed in figure 8.2. There was no significant difference between the control and intervention participant groups at baseline for reported oral health behaviours.

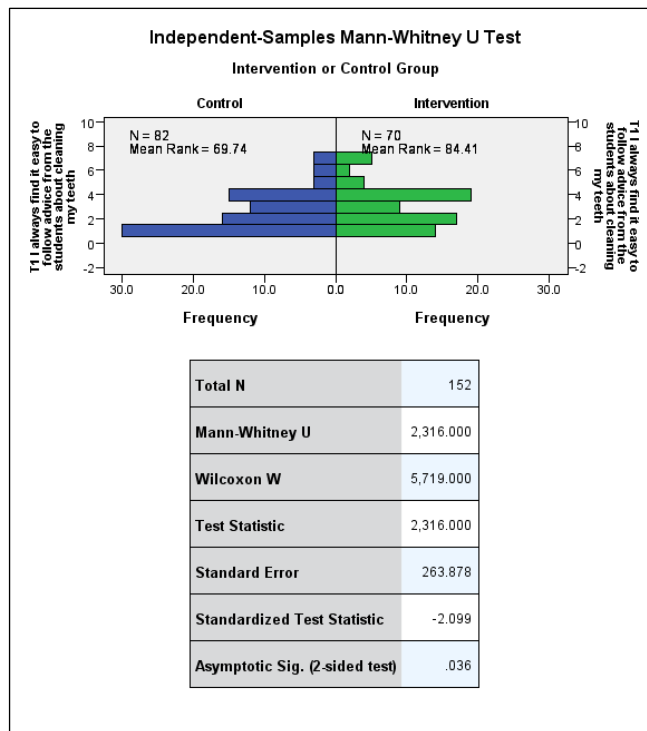


Figure 8.2: results of Independent Samples Mann-Whitney U Test for question 'I always find it easy to follow advice from the students about cleaning my teeth'

8.3.2 Questionnaire Reliability

As the questionnaire questions had previously been utilised by Clarkson, it had already been assessed for validity. The reliability of the questionnaire was however considered. To assess questionnaire reliability similar constructs were grouped together and Cronbach's Alpha calculated. A score of >0.8 is generally taken as an indication of a reliable scale (Kline 1999). Cronbach's Alpha was calculated for the following construct groups:

1. Participant self-efficacy: perceived behavioural control:

Questions: T1Q7a T1Q7b T1Q7c T1Q7d T1Q7e

5 items, Cronbach's Alpha: 0.903 : outcome reliable

2. Participant control belief:

Questions: T1Q8b T1Q8c T1Q8d T1Q8e

4 items, Cronbach's Alpha: 0.801 : outcome reliable

3. Participant subjective norm and behavioural belief, attitude:

Questions: T1Q9a T1Q9c

2 items, Cronbach's Alpha: 0.913 : outcome reliable

4. Participant outcome evaluation: participant attitude towards tooth cleaning:

Questions: T1Q9d T1Q9e T1Q9f T1Q9g T1Q9i

5 items, Cronbach's Alpha: 0.864 : outcome reliable

The questionnaire was considered a reliable tool to measure of the chosen constructs.

8.3.3 DOOHS Participant Questionnaire Reported Oral Health Behaviours

Participants were reviewed at approximately 3 and 6 months after receiving the initial oral hygiene instruction. A number of participants were lost to follow up as discussed in Chapter 7. Some participants returned their questionnaires by post. There were missing responses to some questions. Where the questionnaire was missing, it was excluded from the analysis. Where a single response was missing the mode from the family of constructs was substituted. This explains the varying numbers of responses and returns in the data which follows.

Table 8.7: Number of questionnaire returns by participant group

	Original Group Size	3 Month Returns (%)	6 Month Returns (%)
Intervention	77	58 (75.3)	46 (59.7)
Control	88	63 (71.6)	54 (61.4)

The questionnaire data was analysed using non-parametric tests to assess for significant differences between the reported oral health behaviours of the control and intervention groups in the short (three month) and long (six month) term. A

Friedman's Two-Way analysis of variance by ranks was carried out using SPSS (Field 2009), significance 0.05 was corrected (divided by 2) to 0.025 to account for the two review time points. The results follow in table (8.8).

Table 8.8: Results of the Friedman's Two-Way Analysis of Variance by ranks for reported oral health behaviours

Null hypothesis: The distributions of responses to question through the study: T1, T2, and T3 do not change	Related Samples Friedman's Two-Way Analysis of Variance by ranks		Null hypothesis
	Intervention Significance	Control Significance	
Do your gums ever bleed when you clean your teeth?	0.419	0.219	Upheld
How long do you spend brushing your teeth?	0.013*	0.073	Rejected for the intervention group
How often do you use a manual toothbrush?	0.011*	0.470	Rejected for the intervention group
How often do you use an electric toothbrush?	0.867	0.150	Upheld
How often do you floss?	0.059	0.074	Upheld
How often do you use toothpicks?	0.237	0.636	Upheld
How often do you use brushes between your teeth?	0.094	0.470	Upheld
How often do you use mouthwash?	0.898	0.049	Upheld
How confident are you that you can follow dental student advice about cleaning your teeth?	0.006*	0.749	Rejected for the intervention group
How confident are you that you can clean your teeth so they can't be any cleaner?	0.151	0.314	Upheld
How confident are you that you can clean your teeth as often as you should?	0.989	0.184	Upheld
How confident are you that you can clean your teeth for as long as you should?	0.011*	0.117	Rejected for the intervention group

Null hypothesis: The distributions of responses to question through the study: T1, T2, and T3 do not change	Related Samples Friedman's Two-Way Analysis of Variance by ranks		Null hypothesis
	Intervention Significance	Control Significance	
How confident are you that you can clean your teeth the way that you should?	0.276	0.243	Upheld
I always find it easy to follow advice from the students about cleaning my teeth	0.005*	0.110	Rejected for the intervention group
I would always like to clean my teeth until they can't get any cleaner, but I don't think it's possible for me to do so	0.006*	0.353	Rejected for the intervention group
I would like to clean my teeth as often as I should, but I don't think it's possible for me to do so	0.008*	0.443	Rejected for the intervention group
I would like to clean my teeth for as long as I should, but I don't think it's possible for me to do so	0.826	0.140	Upheld
I would like to clean my teeth the way should, but I don't think it's possible for me to do so	0.991	0.499	Upheld
Cleaning my teeth is a good thing to do	0.031	0.872	Upheld
Cleaning my teeth is a boring thing to do	0.148	0.239	Upheld
Cleaning my teeth makes my mouth feel good	0.002*	0.909	Rejected for the intervention group
The more I clean my teeth the less decay I will get	0.101	0.334	Upheld
The more I clean my teeth the less gum disease I will get	0.060	0.051	Upheld
The longer I clean my teeth the less decay I will get	0.550	0.304	Upheld
The longer I clean my teeth the less gum disease I will get	0.065	0.485	Upheld

Null hypothesis: The distributions of responses to question through the study: T1, T2, and T3 do not change	Related Samples Friedman's Two-Way Analysis of Variance by ranks		Null hypothesis
	Intervention Significance	Control Significance	
The longer I clean my teeth the less my gums will bleed	0.014*	0.233	Rejected for the intervention group
The more I clean my teeth the less my gums will bleed	0.173	0.530	Upheld
I think the dental students want me to clean my teeth differently from how I now clean them	0.878	0.560	Upheld
I don't care how the dental students think I should clean my teeth	0.414	0.297	Upheld
	*result significant p=0.025		

When the correction in the significance level was applied, the only statistical difference between the two groups was seen in the question 'cleaning my teeth makes my mouth feel good'.

The data was further analysed for differences between the control and intervention groups at the time points T1 baseline, T2 (three months) and T3 (six months), using a Mann Whitney U Test for differences in reported behaviour at significance level 0.05.

Table 8.9: Results of the Independent samples Mann Whitney U Test for reported oral health behaviours

Null hypothesis: There is no difference in reported behaviour between the control and intervention groups at time points	Time T1: Baseline T2: 3 months T3: 6 months	Independent Samples Mann Whitney U Test
Do your gums ever bleed when you clean your teeth?	T1	0.493
	T2	0.449
	T3	0.728
How long do you spend brushing your teeth?	T1	0.171
	T2	0.243
	T3	0.102
After brushing do you rinse out?	T1	0.476
	T2	0.271
	T3	0.180
How often do you use a manual toothbrush?	T1	0.150
	T2	0.299
	T3	0.671
How often do you use an electric toothbrush?	T1	0.725
	T2	0.642
	T3	0.718
How often do you floss?	T1	0.497
	T2	0.702
	T3	0.786
How often do you use toothpicks?	T1	0.625
	T2	0.481
	T3	0.670
How often do you use brushes between your teeth?	T1	0.435
	T2	0.429
	T3	0.587
How often do you use mouthwash?	T1	0.267
	T2	0.970
	T3	0.748

Null hypothesis: There is no difference in reported behaviour between the control and intervention groups at time points	Time T1: Baseline T2: 3 months T3: 6 months	Independent Samples Mann Whitney U Test
How confident are you that you can follow dental student advice about cleaning your teeth?	T1	0.278
	T2	0.147
	T3	0.230
How confident are you that you can clean your teeth so they can't be any cleaner?	T1	0.743
	T2	0.910
	T3	0.217
How confident are you that you can clean your teeth as often as you should?	T1	0.464
	T2	0.863
	T3	0.660
How confident are you that you can clean your teeth for as long as you should?	T1	0.461
	T2	0.754
	T3	0.212
How confident are you that you can clean your teeth the way that you should?	T1	0.611
	T2	0.804
	T3	0.530
I always find it easy to follow advice from the students about cleaning my teeth	T1	0.036*
	T2	0.349
	T3	0.635
I would always like to clean my teeth until they can't get any cleaner, but I don't think it's possible for me to do so	T1	0.240
	T2	0.468
	T3	0.390
I would like to clean my teeth as often as I should, but I don't think it's possible for me to do so	T1	0.443
	T2	0.345
	T3	0.556
I would like to clean my teeth for as long as I should, but I don't think it's possible for me to do so	T1	0.632
	T2	0.916
	T3	0.145
I would like to clean my teeth the way should, but I don't think it's possible for me to do so	T1	0.612
	T2	0.791
	T3	0.779

Null hypothesis: There is no difference in reported behaviour between the control and intervention groups at time points	Time T1: Baseline T2: 3 months T3: 6 months	Independent Samples Mann Whitney U Test
Cleaning my teeth is a good thing to do	T1	0.330
	T2	0.875
	T3	0.321
Cleaning my teeth is a boring thing to do	T1	0.234
	T2	0.626
	T3	0.997
Cleaning my teeth makes my mouth feel good	T1	0.318
	T2	0.210
	T3	0.253
The more I clean my teeth the less decay I will get	T1	0.369
	T2	0.498
	T3	0.047*
The more I clean my teeth the less gum disease I will get	T1	0.287
	T2	0.892
	T3	0.254
The longer I clean my teeth the less decay I will get	T1	0.379
	T2	0.789
	T3	0.601
The longer I clean my teeth the less gum disease I will get	T1	0.146
	T2	0.504
	T3	0.466
The longer I clean my teeth the less my gums will bleed	T1	0.201
	T2	0.957
	T3	0.684
The more I clean my teeth the less my gums will bleed	T1	0.240
	T2	0.945
	T3	0.689
I think the dental students want me to clean my teeth differently from how I now clean them	T1	0.779
	T2	0.786
	T3	0.474

Null hypothesis: There is no difference in reported behaviour between the control and intervention groups at time points	Time T1: Baseline T2: 3 months T3: 6 months	Independent Samples Mann Whitney U Test
I don't care how the dental students think I should clean my teeth	T1	0.650
	T2	0.452
	T3	0.291

*Significant value $p=0.05$

Taking the reported behaviours as separate questions no significant difference was found between the control and intervention oral hygiene instruction groups.

The full results are displayed as a series of bar charts within Appendix 18.

8.3.4 Application of the Question Constructs Linking to the Theory of Planned Behaviour Methodology

The data from the constructs previously outlined (table 8.1) was synthesised as follows:

- Questions 8b, 8c, 8d, 8e measuring control belief were reverse scored using SPSS to account for the negative questions
- 9b was reverse scored.
- 10b was also reverse scored before adding to 10a to give an overall score for subjective norm.
- 6a, 6b, 6c and 6e were reverse scored so that a high scoring behaviour was increased frequency of cleaning behaviour.

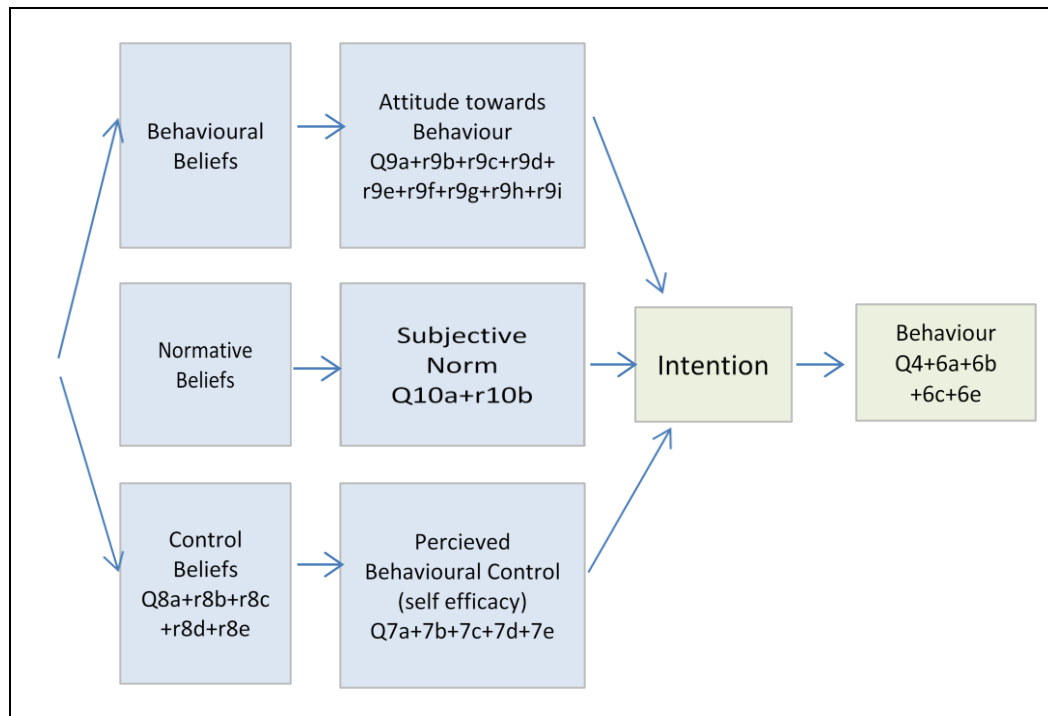


Figure 8.3: Application of DOOHS questionnaire constructs according to Ajzen's Theory of Planned Behaviour

The mode of the covariables is taken for each construct and an overall value given for the following: beliefs, subjective norm, and attitude. These can be added together to give an intention score for each participant which is analysed in relation to their reported oral health behaviour. Analysis of the responses from the DOOHS participants was carried out, however, the results proved to be meaningless. This may have been due to the spread of the answers given for the self-efficacy questions which, as discussed later, the outreach participants reported as confusing, or it may have been due to the low numbers of participants in this study. The discussion therefore focuses on the participant questionnaire and the behaviours as individually reported.

8.3.5 Participant Oral Health Behaviour Questionnaire Discussion

The participant questionnaire had several problems.

The return rate was disappointing - some of the questionnaires were not collected by students. This was seen first-hand by the author when participants presented with the

questionnaire in their hand and the student then ignored it during the appointment until prompted by staff. Questionnaires for participants who failed to return for review were mailed out by SDCEP. These questionnaires saw a 40% return rate. This was a useful way of capturing further data which could have been lost to follow up.

The students fed back that participants found the questionnaire too long. The questionnaire relied on self-reported oral health behaviours. The participants who enrolled in DOOHS are a self-selecting sample of outreach patients. They presumably signed up to DOOHS because they had some interest in the subject of oral hygiene or at least prevention. They are not necessarily reflective of outreach patients in general. The questionnaire contained questions about both oral health behaviours and about their experience as participants during DOOHS. On reflection it may have been easier for participants to have two separate but shorter questionnaires. It may have been best to have these mailed out directly to outreach participants rather than relying on outreach clinics to hand them to outreach participants before their study appointment. At the clinics where one particular member of staff had taken responsibility for DOOHS, this method worked well, however at the other clinics, nobody seemed to be aware of who was responsible. Ultimately, nobody took responsibility in these situations and the questionnaire was often handed over at chair side which could have potentially influenced responses as the participant was, by then, sitting in the dental chair. Having a dedicated outreach nurse or member of outreach staff could have resolved this problem.

Although the questionnaire had been previously used in general practice, some of the questions within the questionnaire were long and the wording not straightforward to understand e.g. "I would always like to clean my teeth until they can't get any cleaner, but I don't think it's possible for me to do so". This was to reflect the theory of planned behaviour model constructs, however some outreach participants wrote comments on the questionnaire that they didn't understand particular questions. This could explain the spread of responses across such questions. Participants indicated this was the case for several questions so more than one construct was affected.

There were also problems in the reported oral health behaviours across items such as the use of an electric toothbrush, a manual toothbrush, floss and interdental brushes. Participants could easily indicate that they occasionally used an electric toothbrush and occasionally used a manual toothbrush however we don't know what the participant means by 'occasionally' and it is possible that once all the 'occasions' are added together that we have someone who is actually cleaning regularly, just with different items. It would have been more useful to have the categories grouped together into tooth brushing (all types) and interdental cleaning with a list of the options. For the purpose of this study it was not essential to know the items the participants were using, just that they were reporting carrying out oral health behaviours and their frequency. This could explain why, when the modes to the question responses were calculated and fed into the theory of planned behaviour model, no meaningful result was obtained.

The participant reported oral health behaviours found no statistical significance between the control and the intervention groups at baseline. The two groups were then followed forward through the three and six month reviews to find whether their reported health behaviours changed after the groups received their intervention and control oral hygiene instruction. The application of a Bonferroni correction (Sedgewick 2014), to compensate asking the same question over the three- and six-month reviews, rendered the change in reported oral health behaviours for both groups not significant. However, if we look at the differences between the significance levels for the control and intervention groups there is a large difference between the two groups for several constructs.

The intervention group had higher reported confidence in carrying out oral health behaviours (self-efficacy). They also had stronger beliefs in their control over bleeding: 'the longer I clean my teeth the less my gums will bleed': 0.014 (intervention) versus 0.233 (control).

The response to the question 'the more I clean my teeth the less decay I will get' was found to be statistically significant between the control and intervention groups at six

months (T3). With so many constructs and time points, this is most likely to be a chance finding.

If we look at questions such as the time spent brushing, this appears to increase as the study time increases. However, such results should be treated with caution as it is likely that the participants remaining in the study at the end are those who are more interested in the study topic and therefore spend more time on their oral health.

8.4 Plaque and Bleeding Scores

Plaque was measured to give an indication of the participants' oral hygiene compliance. Participants' bleeding scores were measured to investigate any change in periodontal health of the dental outreach participants.

8.4.1 Method of Analysis of Plaque and Bleeding Scores

As the plaque and bleeding scores were measured as percentages and are bound by 0% and 100%, the data must therefore be treated as ordinal and non-parametric tests were indicated. The plaque and bleeding scores had been recorded for the intervention and control participants at three time points (baseline, three months and six months). The file was split into intervention and control groups and, as the samples are related, Friedman's ANOVA was completed on the data (Field 2009).

As there were multiple tests applied to the same question a Bonferroni correction (Sedgewick 2014) was applied to control type 1 error. This was applied to the usual criterion p-value of a single test being significant at 0.05 by dividing by the number of times the test is applied. As two tests were conducted in this case, a significance level of 0.05 was divided by two to compensate for the repeated measures giving corrected significance level of 0.025, ($0.05/2=0.025$).

8.4.2 Results – Plaque and Bleeding Scores

Table 8.10: Plaque and bleeding statistical analysis results

Intervention group	Null hypothesis	Test	Significance	Result
Plaque	There is no difference in the distributions of baseline, 3 month and 6 month plaque scores %	Related samples Friedman's Two-Way Analysis of Variance	0.002	Reject null hypothesis
Bleeding	There is no difference in the distributions of baseline, 3 month and 6 month bleeding scores %	Related samples Friedman's Two-Way Analysis of Variance	0.221	Retain null hypothesis
Control group	Null hypothesis	Test	Significance	Result
Plaque	There is no difference in the distributions of baseline, 3 month and 6 month plaque scores %	Related samples Friedman's Two-Way Analysis of Variance	0.170	Retain null hypothesis
Bleeding	There is no difference in the distributions of baseline, 3 month and 6 month bleeding scores %	Related samples Friedman's Two-Way Analysis of Variance	0.071	Retain null hypothesis

Significance level 0.025

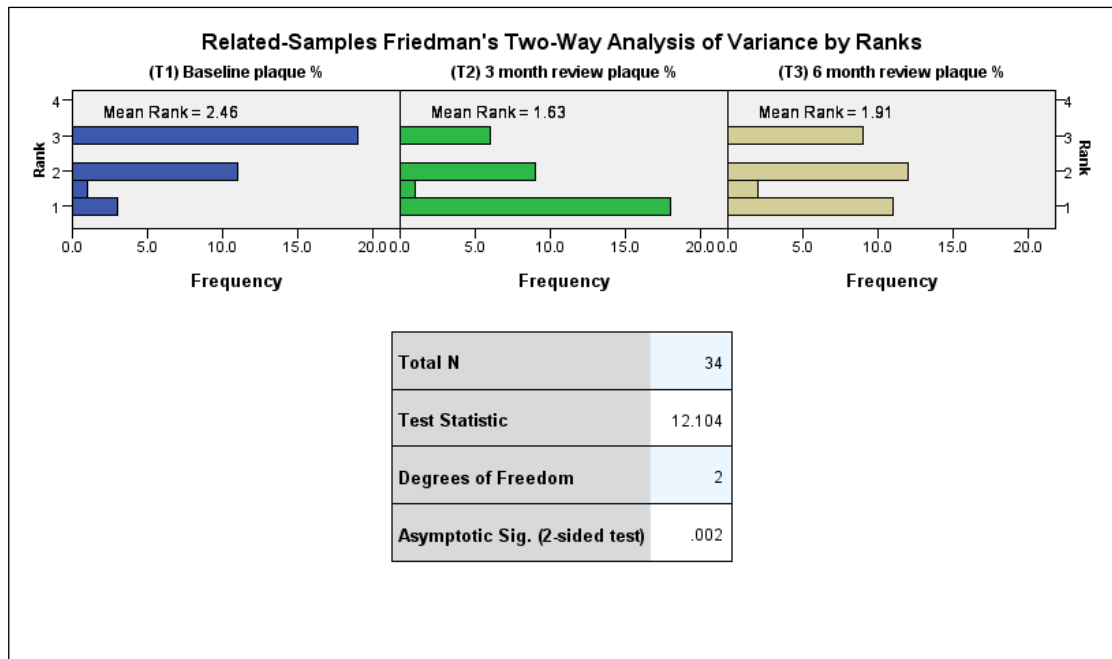


Figure 8.4: Intervention group plaque scores during DOOHS

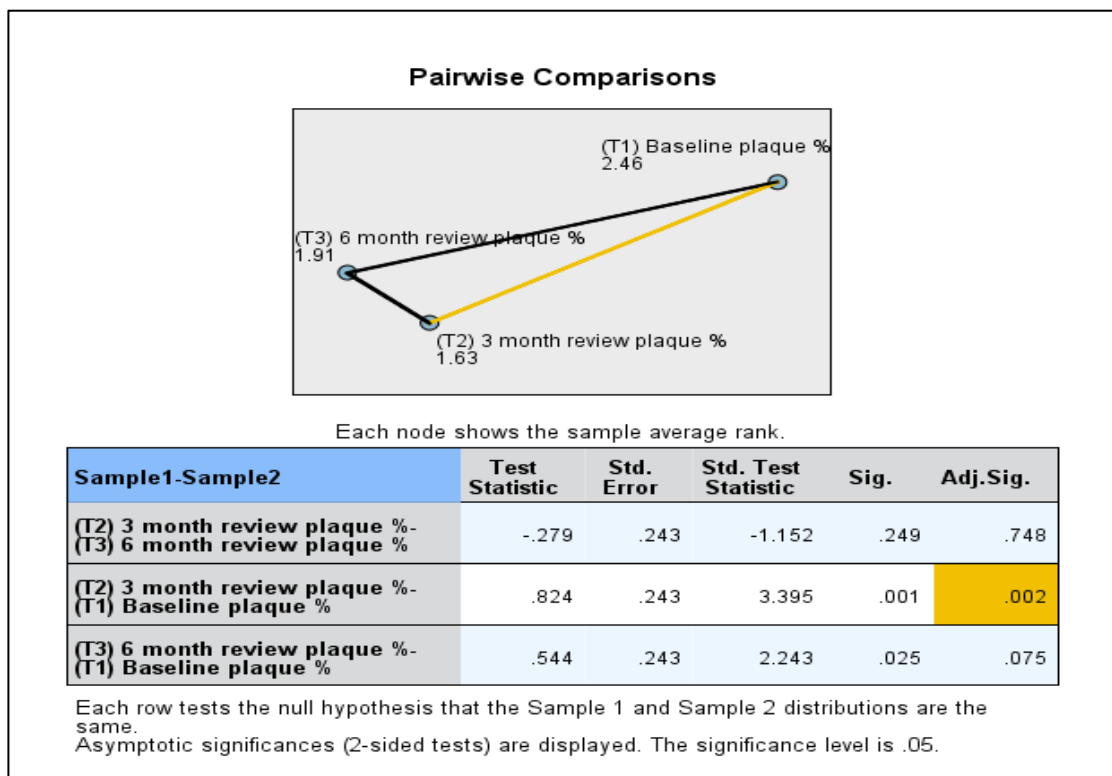


Figure 8.5: Intervention group plaque scores during DOOHS showing significant reduction at 3 months

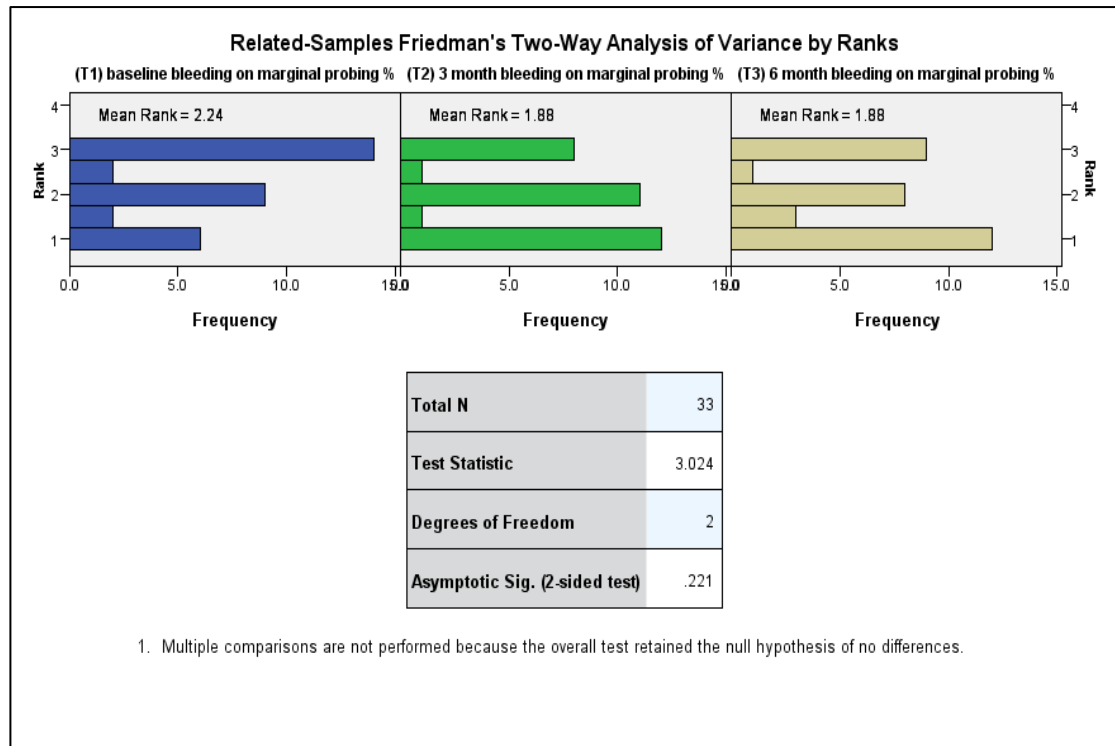


Figure 8.6: Intervention group bleeding scores during DOOHS

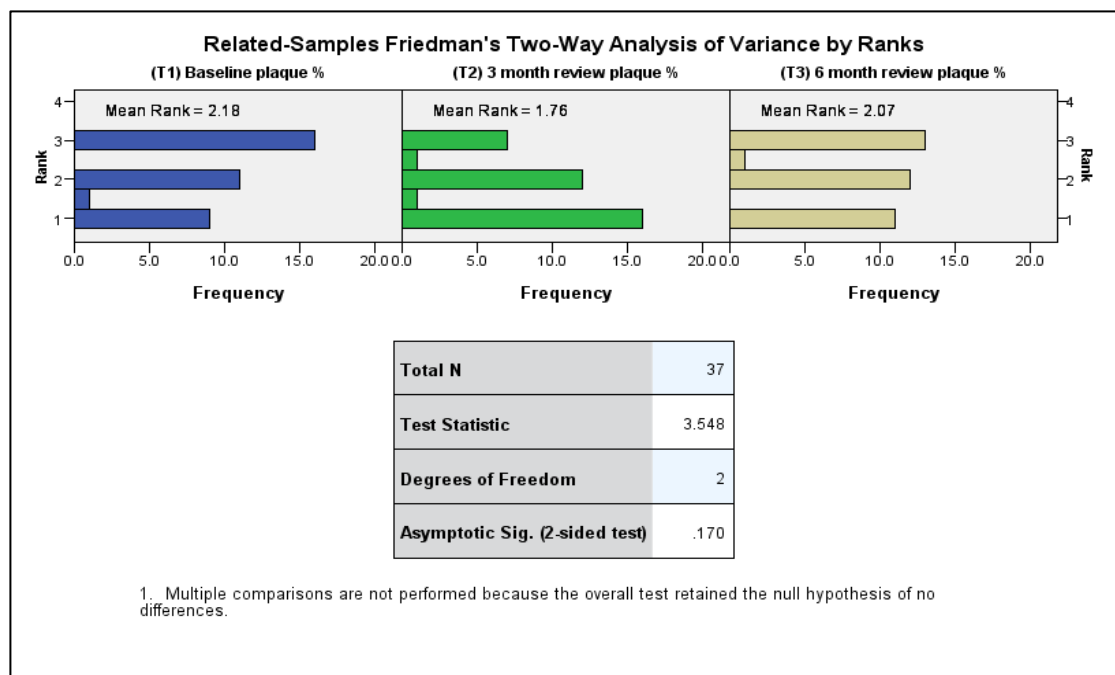


Figure 8.7: Control group plaque scores DOOHS

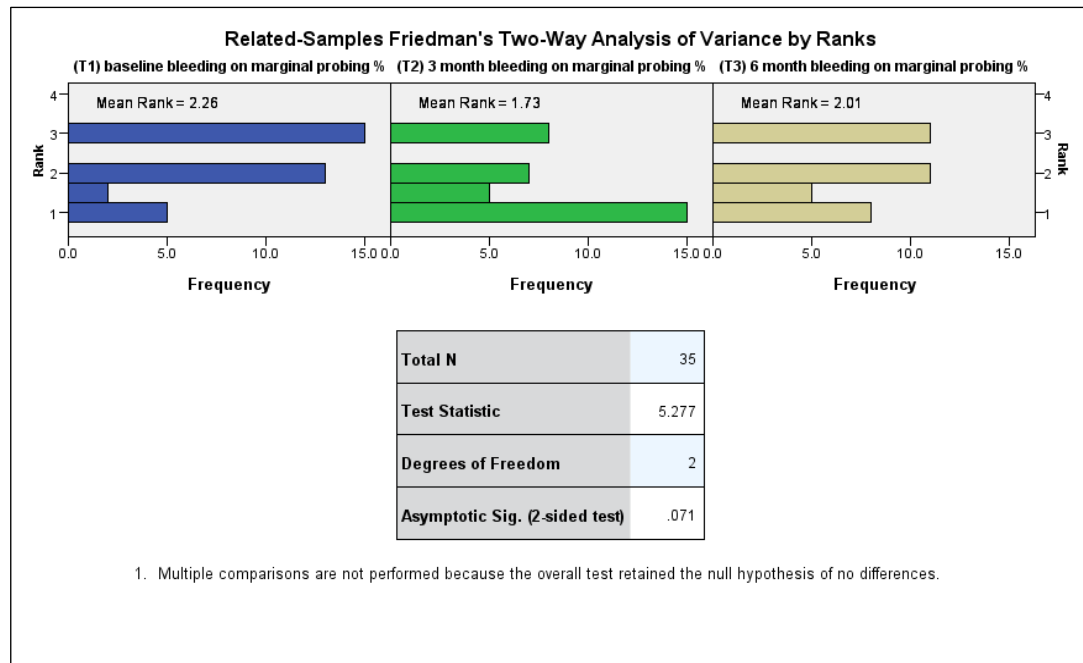


Figure 8.8: Control group bleeding score during DOOHS

8.4.3 DOOHS Plaque and Bleeding Discussion

Both the intervention and control groups saw a reduction in plaque scores at three months. This was statistically significant for the intervention group. At six months plaque reduction was still evident when compared to baseline for both groups however was no longer statistically significant for the intervention group and at six months the control group plaque scores were almost back to their baseline level. This is similar to findings from other studies into oral hygiene instruction (Axelsson & Lindhe, 1981). The bleeding on probing scores were not statistically significant for either the control or intervention groups at three or six months, indicating no change in oral health for either group.

The measurements were being taken by dental students thus, the O'Leary charts had been selected for use during DOOHS. The benefit of such charts was that the students were already familiar with them. However, the O'Leary charts are dichotomous and are not, by nature, very sensitive for measuring changes in plaque scores. Each surface is only measured as having plaque present or absent and small, per-surface changes, such as a reduction in plaque, are not recorded.

The lack of reduction in bleeding scores suggests there was no oral health improvement for either control or intervention oral hygiene instruction. There are however many possible reasons why the bleeding scores did not improve. The study took no measure of the patient's susceptibility to periodontal disease, baseline periodontal disease in terms of pocket depth, their diet, nor their general health, all of which could impact on bleeding scores.

The improvement in plaque scores for the intervention group ties in with the results of the Cochrane review into "Psychological interventions to improve adherence to oral hygiene instructions in adults with periodontal disease" (Renz 2007) and also the SDCEP oral hygiene TIPPS information from the guidelines entitled, "Prevention and Treatment of Periodontal Diseases in Primary Care" (SDCEP 2014). These advise that incorporation of planning into a patient's oral hygiene instruction increases the likelihood that they will carry out the oral health behaviour. For DOOHS, the control group did not have this as a normal part of oral hygiene instruction as it was not, at the time, included in the teaching by the Periodontology Department (DOOHS was run before the publication of the SDCEP TIPPS advice). The intervention group, with the introduction of planning into their oral hygiene instruction saw plaque reduction for participants at 3 months and although the bleeding scores reductions were not statistically significant, these patients would have reduced their risk of dental diseases such as caries and periodontal disease. The fact that the improvement was not sustained in the long term (six months) supports the body of evidence that OHI should be repeated regularly to patients (Axelsson & Lindhe 1981).

8.5 Results Impact of DOOHS on Outreach Patient Care

During the implementation of the Dental Outreach Oral Hygiene Study attention was paid to the impact on the provision of dental patient care. One of the concerns for outreach staff was that the study would 'get in the way' of patient care provision (Chapter 4) and the final year students were concerned about their productivity and gaining experience prior to graduating. The provision of dental treatment was assessed in three ways:

- i. The Dental Outreach Reports (Watt 2010, 2012, 2014)
- ii. Case report forms from DOOHS
- iii. Manual check of participant's notes by the author during site visits

The Dental Outreach Reports (Watt 2010, 2012, 2014) are annual reports detailing the number and type of treatment carried out on outreach clinics. At the time of DOOHS, the data which fed into this report was collected using a paper form which outreach supervisors completed for each student, each day, to record their clinical activity. This form consisted of a series of boxes which were ticked to indicate the student had carried out particular procedures, the function of this form was to record the student's clinical experience. The forms were submitted to the outreach coordinator Bruce Watt who collated the student experience and puts together the yearly Dental Outreach Report for NES.

DOOHS Case Report Forms had a section included for each visit where student researchers could write down brief details of dental treatment carried out at the same time as the clinical research visit.

The participant's electronic R4 dental notes were checked at each outreach clinic. As these notes are completed each time a patient attends for treatment it was straightforward to check if any dental treatment had been carried out at the same time as the CRF was checked for the participant. These notes were an accurate record of treatment carried out. Though laborious, the author was already examining the notes for accuracy of dates and charts during site visits, and as such a further check was simple to complete. These electronic R4 patient notes were additionally examined by the author during site visits to give an indication of the accuracy of the CRF completion.

The Case Report Forms proved to be a relatively unreliable way of tracking what had been carried out alongside the research. The author found discrepancies between what had been noted on the CRF and what was in the patient's electronic notes for a particular visit. Students tended to under-report, or fail to report, the treatment carried out. The reasons for this were discussed with outreach staff who

were of the view that the box wasn't completed as it was considered an additional thing to do and not essential to the clinical research study. It is also probable that the CRF would have been completed and filed before the patient received any dental care as the clinical measures were to be taken at the start of the appointment before any dental treatment was carried out as per the study protocol.

Checking the notes on R4 was helpful to establish why some participants had vanished from the study. Two participants were found to have attended in pain which was treated and a further appointment was made for the clinical research study as per the protocol. In other cases, participants attended for a study visit but did not have their measures completed. In one case, the participant attended 10 times for routine care and no plaque or bleeding measures were recorded. This was noted on the particular participant's questionnaire by the participant themselves. The reasons for participants having their measures missed were unclear. However, when students were questioned on the outreach clinics they explained that they sometimes had difficulty in working out who was actually enrolled in DOOHS. The R4 DOOHS icon was not always added to the patient's electronic notes and, at one site, kept being removed by the IT department. The sites with the greater return rates were those where the outreach staff had kept a separate note of patients enrolled in DOOHS and directly told the students what the patient was attending for each session. Future studies in outreach should not rely on students keeping track of participant reviews through the dental notes. Separate logs are required to ensure that reviews are carried out at the correct visit.

The most reliable reflection of the number of dental procedures carried out in the outreach clinics during DOOHS was the annual outreach monitoring report (Watt 2010, 2012, 2014), (Appendix 19).

When the outreach monitoring report for the years around DOOHS is explored, there was an increase in the overall number of procedures carried out in outreach by dental students during the time of the study (2010-2011 and 2011-2012), table 8.11.

Table 8.11: Dental outreach monitoring report excerpt for years around DOOHS

Year	Total number of procedures carried out in outreach	Number of oral hygiene instructions/ preventive advice	Number of plaque/ bleeding charts	Number of patient contacts
2009-2010	38,008	1,123	71	13,189
2010-2011	42,844	1,353	180	14,447
2011-2012 *	50,703	2,063	320	16,055
2012-2013	39,408	1,074	184	12,912

*New outreach clinic Broxden opened this year which results in the large increase in numbers.

Not only were the overall number of dental procedures carried out during DOOHS greater than the previous year, but the number of preventive advices given increased. There was a 127.8% increase in recording of outreach patient's periodontal health (plaque and bleeding indices). Overall DOOHS had a positive impact on the preventative dental care delivered in the dental outreach clinics.

8.6 DOOHS Conclusions

Providing oral hygiene instruction within a psychological framework may provide a significant reduction in the plaque levels recorded from dental outreach patients in the short term when compared to patients receiving the usual forms of oral hygiene instruction delivered on the clinics.

Dental outreach clinics need a designated member of staff if they are to carry out clinical research studies in outreach. This member of staff would have responsibility for organising the review appointments for outreach participants and any questionnaires relating to the clinical research study. Clinical studies in which measures are recorded over a short (<three months) timescale may be better suited to dental outreach and the undergraduate curriculum. Questionnaires should be piloted on a group of outreach patients before use in a clinical research study in outreach, even if they have previously been utilised in the primary care dental setting.

Clinical research studies in outreach can expect to recruit a maximum of 165 participants over a three month period when involving six sites. Starting recruitment at the beginning of the academic year would afford students a greater opportunity of following participants through the study and would additionally allow the recruitment phase to be lengthened as required. It is unlikely clinical research studies in outreach can recruit the large numbers of participants required for cluster trial. This is due to the repeat appointments each outreach patients attends in order to complete their treatment. The throughput of new patients is too slow in outreach.

Clinical research studies in outreach provide an opportunity to highlight a certain area of dental care (in this case prevention) and give students opportunity to focus more on a particular area for the duration of the study. There is some evidence from the dental outreach reports that this is sustained for a period after the completion of the research.

In summary, short term clinical research studies requiring small numbers of patients are feasible in dental outreach.

Chapter 9: Exploration of Views following Direct Involvement in the Clinical Research Study

During the post-study exploration, DOOHS participants, final year dental students, dental outreach staff, and outreach patients were consulted in order to explore views towards clinical research in dental outreach following direct involvement with the study.

This consultation was carried out using:

- Final year student questionnaires (Section 9.1)
- Focus groups with final year students (Section 9.2)
- Outreach staff questionnaires (Section 9.3)
- DOOHS participant questionnaires (Section 9.4)

This consultation addressed the following objectives:

- Exploration of views of students, and staff towards advantages and disadvantages of clinical research studies in dental outreach
- Explore the views of outreach participants who had taken part in the study
- Exploration of barriers to, and facilitators towards the conduction of clinical research studies in outreach clinics as viewed by student researchers and dental outreach staff
- Inform future research studies in dental outreach clinics

9.1 Post Study Final Year Student Questionnaires

9.1.1 Post-Study Final Year Student Questionnaire Objectives

The final year student questionnaire addressed the following objectives:

- exploration of the students' perceived advantages and disadvantages of clinical research in dental outreach
- exploration of the students' perceived barriers and facilitators towards clinical research in dental outreach.

9.1.2 Post-Study Final Year Student Questionnaire Methodology

Paper questionnaires (appendix 20) were distributed to the initial (recruiting) group of final year students who had collaborated with DOOHS by the dental school administration. These were in sealed envelopes. The students were asked about i) their experiences during DOOHS and ii) their views on clinical research in dental outreach.

Questionnaires were returned to the dental school office, the author directly or the SDPBRN office in sealed envelopes (provided). Students were responsible for the return of their questionnaires.

The data from the student questionnaires was collated by SDPBRN and passed to the author for analysis.

9.1.3 Post-Study Final Year Student Questionnaire Methodology of Analysis

The data from the student views regarding clinical research in dental outreach were input into excel and transferred into SPSS. The post-study questionnaire additionally collected data regarding dental student attitudes to oral hygiene instruction. For the purposes of this thesis only the clinical research responses were

relevant. The data was transferred into a table (table 9.1) displaying the inclination of the student views for each area. After assessing for normality of distribution, the data was found not to follow a normal distribution curve, possibly due to the low response rate of the questionnaire. It is assumed most likely that students returning the questionnaires were those with strongest opinions concerning their experience of clinical research. The strong positive and negative opinions therefore offered polarised responses. For the purpose of tabulation the 7 point Likert scale has been simplified to 5 points with the two most extreme points at either end of the scale grouped together. To assist the reader, these views have been coloured to highlight the area where the responses were strongest. Where there was a split response the row has been left blank. The red colour is utilised to highlight negativity towards clinical research in dental outreach and green for positivity, blue indicates a neutral response overall is held.

Free text responses were grouped into themes and the number of comments given from the students in each theme is given in brackets after the theme.

9.1.4 Post-study final year student questionnaire findings

Questionnaires had a disappointing low rate of return 36/67 (53.7%). The low rate of return may have been responsible for the responses not following a normal distribution curve. Student responses to the questions follow. These have been grouped into the categories as follows:

- Student responses in relation to their experiences during DOOHS
- Student views on clinical research in dental outreach.

Student responses in relation to their experience during DOOHS

Table 9.1: Student post-study responses: student experience during DOOHS

In regard to this clinical study:	Strongly disagree		Neutral		Strongly agree	Missing
I gave advice about oral hygiene as required	1	0	3	2	27	3
I demonstrated oral hygiene techniques as required	1	0	3	2	29	1
I coped with what was required as a researcher	1	2	8	4	20	1
In general carrying out this study made me more confident about:	Strongly disagree		Neutral		Strongly agree	
Giving advice about oral hygiene	13	4	6	2	11	
Demonstrating oral hygiene techniques	13	4	7	5	7	
Coping with taking part in a clinical study	6	4	10	5	11	
Inviting patients to participate in research	2	11	4	8	11	
Fitting extra time required for research into patient appointments	15	5	8	4	4	

In general carrying out this study made me more confident about:	Strongly disagree		Neutral		Strongly agree	
Following the protocol of a clinical study	4	6	9	10	7	
Starting research projects of my own	23	5	4	2	2	
How many patients did you recruit to the study?	0 patients=5	1 patient =9	2 patients=9	3 patient s =6	4 patients=3	5 patients =4
How many information packs did you give out?	4=5 packs, 3=6 packs, 2=7 packs, 1=9 packs, 4=10 packs, 4=11 packs, 3=12 packs, 2=13 packs, 1=14 packs, 5=15 packs, 1=16 packs, 1=17 packs, 1=18 packs, 3=20 packs, 1=25 packs (total 402 packs)					
During the study:						
Did you have time to carry out research activities and patient treatment at the same appointment?	Never 5	Rarely 9	Sometimes 10	Usually 5	Always 5	Missing 2
	Strongly disagree				Strongly agree	
I had all the information I needed	10	2	7	7	10	
It was easy to follow the protocol	12	6	4	8	4	2
There was minimal disruption to the patient appointments	23	8	0	2	3	

	Strongly disagree				Strongly agree	
I was confident carrying out the study procedures without help	8	7	1	3	16	1
I was given all the help I required to follow the protocol from outreach staff	3	6	8	7	9	3
I was given all the help I required to follow the protocol from research staff	3	3	6	6	18	
I was confident answering patient questions about the study	4	3	7	11	11	
I was confident in my knowledge of consent procedures	4	7	7	5	13	
I was confident in filling in and returning the study paperwork	11	6	6	3	9	1
I was confident in delivering oral hygiene instructions/advice	0	0	3	6	26	1
I felt out of my depth more than usual	12	3	10	6	5	
I often ran late	3	3	9	7	14	
The outreach patients were enthusiastic	11	6	7	5	5	2
The outreach staff were enthusiastic	10	5	10	6	5	

	Strongly disagree				Strongly agree	
I effectively managed the time required for the trial during the appointment times	9	4	9	10	4	
I recruited as many patients as I wanted to	16	3	8	1	8	
I recruited as many patients as I was required to	23	0	4	0	9	
If you needed help who did you ask?	Other students=3, outreach staff=2, researcher=1, no help required=1, missing=1, combination of dental nurses and other=28					
Clinical research during outreach:	Strongly disagree		Neutral		Strongly agree	
Was enjoyable for me	23	8	3	1	1	
Improved my future employment opportunities	19	5	3	7	2	
Taught me new skills	5	4	7	6	12	
Was confusing	12	7	10	4	3	
Was stressful	6	3	8	9	10	
Improved my understanding of research	12	3	8	5	8	
Was of benefit to me	20	3	7	3	3	

Key	
	Positive Majority Response
	Neutral Majority Response
	Negative Majority Response

What was the most difficult part of carrying out the study?

27/36 students responded with comments, some comments covered more than one theme. Themes:

Paperwork (16) :

“All the paperwork making sure everything had been completed & recorded correctly.”

“The extensive paperwork.”

Recruiting patients (8):

‘Not enough patients.’

Time taken up doing the study (8):

“The length of time taken up by doing this.”

“The time - takes ages.”

Carrying out the study alongside patient treatment (1):

“Trying to carry out treatment & do the study in 1 appt.”

What was the best part of being involved in the study?

14/36 students responded with a comment. Themes:

Experience of research (6):

“Knowing I was contributing to it (research)”

“Insight into how impracticable research can be and now I no longer think it’s a simple thing to do.”

“Insight into how a study works.”

“Gaining experience of research.”

Prevention (5):

- “Reducing plaque levels.”*
- “Giving oral hygiene advice.”*
- “Giving OHI.”*
- “Focussing on prevention.”*
- “Learning an alternative way to do OHI.”*

Patient experience (3):

- “Interacting with patients.”*
- “Engaging with patients.”*
- “Patients being involved that were keen.”*

Career development (2):

- “Adding to CV.”*
- “Good for CV.”*

Which part of the study did you find the easiest to cope with?

28/36 students responded with a comment, some of the comments covered several themes. Themes:

Giving oral hygiene instruction (15):

- “Demonstrating oral hygiene methods.”*
- “Delivering oral hygiene advice.”*
- “Giving advice and demonstrating.”*

Giving out patient information/ informing patients about the study (8)

- “Handing out packs.”*
- “Asking patients to get involved.”*
- “Explaining the study.”*

Charting (7):

- “Doing the actual charts.”*
- “Recording plaque and bleeding”*

“Baseline readings.”

Other (1):

“Largely similar approach between centres.”

Which part of the study did you find the most difficult to cope with?

32 students responded with comments, some comments covered multiple themes.

Themes:

Time it took to complete paperwork and paperwork (19):

“Excessive paperwork which seemed very repetitive & time consuming.”

“The endless paperwork completing all the forms correctly & putting them in the right place.”

“Time to recruit/ fill in paperwork.”

“Paperwork, time management.”

Recruiting patients (8):

“Managing to recruit eligible pts.”

“Getting people to return packs.”

“Recruiting enough pts.”

“Remembering to hand out packs.”

Communicating aspects of DOOHS to patients (5):

“Explaining consent”

“Explaining things to patients”

“Explaining to pts that they will have to make another appointment despite all treatment being finished.”

“Explaining what was going to happen to patient.”

Outreach staff support (3):

“Lack of interest from supervisors.”

“Greatly dissimilar approach to protocol implementation.”

“Lack of help from outreach staff as they didn't really know protocol.”

Which part of the study did you find the least time consuming?

30 students responded with comments. Themes:

Patient information (pack) distribution (13):

“Giving out packs.”

“Handing out packs.”

“Giving out the information packs & inviting pts to participate.”

“Giving out the consent pack.”

Delivering oral hygiene instruction and advice (9):

“Oral hygiene advice.”

“Giving oral hygiene instruction.”

“Demonstrating oral hygiene instruction.”

Recording plaque and bleeding (5):

“Data collection.”

“Recording plaque and bleeding scores.”

“The actual charts.”

Consent and communication with patients (5):

“Discussing the study”

“Getting consent.”

“Explaining the study.”

Which part of the study did you find the most time consuming?

30 students commented, some comments span several themes. Themes:

Paperwork (19):

Paperwork - filling it in & filling it correctly.

Negotiating paperwork.

"Filling in paperwork."

"Paperwork."

Data collection – plaque and bleeding charts (7):

"Plaque & bleeding charts."

"Plaque and bleeding scores."

"Charting."

Consent (4):

"Doing the consent paperwork."

"Consent."

Recruiting (4):

"The first visit after returning packs."

"Recruiting."

"Baseline visit."

Time (2):

"Didn't have time to recruit the only patient who came back with a pack."

"Fitting in patient's treatment."

Student views on clinical research in dental outreach

Table 9.2: Dental student post-study responses: clinical research in general

For me taking part in clinical research is:	Stressful 11	7	Neutral 13	3	Pleasant 2	Missing
	Embarrassing 3	5	Neutral 15	3	Encouraging 10	
	Difficult 5	4	Neutral 14	7	Easy 6	
	Not something I should do as a dental student 14	4	Neutral 7	4	Something I should do as a dental student 6	1
In general I feel under pressure to take part in research from:	Not at all		Neutral		Very much	
Outreach patients	29	4	2	0	1	
The dental curriculum	11	4	5	4	12	
Dental supervisors/consultants	6	8	7	3	11	1
Researchers	1	2	3	5	25	

In general how motivated are you to do what:	Not at all		Neutral		Very much	
patients think you should	2	4	6	11	13	
the dental curriculum says you should	1	0	5	11	19	
dental supervisors/consultants do	0	1	3	6	24	2
researchers think you should	8	5	9	6	8	
In dental outreach research studies how important is it to you that:	Not at all		Neutral		Very much	
The research topic is relevant to outreach patients	1	1	6	5	23	
The instructions are easy to follow	2	0	1	5	28	
You can carry out normal patient treatments during research appointments	0	3	1	1	31	
Your input is recognised	4	0	7	4	21	
Outreach patients are enthusiastic	1	0	10	6	19	
Outreach staff are enthusiastic	2	1	6	7	20	

	Strongly disagree		Neutral		Strongly agree	
Dental undergraduates should have the opportunity to carry out clinical research during outreach	6	6	11	8	5	
Dental undergraduates can achieve the skills required to carry out clinical research during outreach placements	10	5	9	6	6	
Taking part in clinical research should be part of the undergraduate curriculum	4	1	6	0	25	
Dental outreach clinics are a good research environment	16	6	3	7	4	
I intend to take part in clinical research in the future	19	5	4	5	3	

Key	
	Positive Majority Response
	Neutral Majority Response
	Negative Majority Response

If you could choose a topic for a future clinical research study in outreach what topic would you suggest?

8 student responses:

Success and failure of root canal treatment (2)

Dentures, quality of life with dentures (2)

Caries removal techniques (1)

Success and failure of composite restorations (1)

Smoking cessation (1)

Failed appointments (1)

General comments from the students on the post study questionnaires

General comments focussed on the students' unhappiness with clinical research being compulsory for their final year. Students felt strongly that their collaboration should have been optional, not compulsory, and that the selling of the research experience had been approached badly. The students returning post study questionnaires did however appreciate the opportunity of experiencing clinical research. Two of the students expressed the view that they would be better spending time carrying out dental treatment at that point in their dental education, not carrying out clinical research.

"I felt time spent doing research would have been better spent doing treatment."

"At this stage of our careers, carrying out treatment is far more important than participating in a study. Most of us aspire to be GDPs, not researchers."

"Opportunity - Compulsory compliance wrong approach."

"I feel students should have the option of taking part in research but I don't feel it should be a requirement."

Two of the students gave detailed views regarding their experience

Student 1:

“On the whole I am glad to have had the chance to take part. I felt the way it was sold to the student body was poor & this caused a lot of resentment. We were told we HAD to take part in this study. My biggest irk was the exhaustive bureaucracy of paperwork to fill in. I sympathise with how difficult it must have been to satisfy all the ethics & "best practice" guidelines which I believe were probably the cause of the tidal wave of paper that needed filled in for each patient, then processed & filed correctly. Taking part in this study has confirmed to me that I would prefer to steer clear of research in my dental career - I do not think for a moment you will get all the reward for the phenomenal effort you put into this, as such I reckon I can achieve more "good" in my career in clinical practice. I would not have the patience for research. I hate bureaucracy & for me this is what ruined this project by making it over complicated there has to be a simpler way to perform research or very few undergraduates will ever consider an academic career researching.”

Student 2:

“I remained enthusiastic in regard to the study despite the large proportion of the years' unhappiness. Research is important. Perhaps if I was in "charge" I would have made a greater attempt to encourage students & "invite" students to take part. The element of volunteering applied absolutely to patients but was never extended to "researchers". To carry out clinical research I would feel it essential that those involved actually were committed for the correct reasons. I also felt that there should be more engagement regarding understanding clinical research & we should not merely be used to collect data. I fully support clinical research in the curriculum but in modifications to improve the learning experience. Many thanks.”

9.1.5 Post-Study Final Year Student Questionnaire Discussion

36/67 dental student post study questionnaires were returned. This low rate of return may be due to several reasons:

- The timing of the questionnaire distribution was very close to the finals examinations therefore many students may have not wished to spend time completing and returning a questionnaire at this time,
- The timing of the questionnaire was close to job interviews for the final year therefore their focus at this time was on securing a vocational training position,
- Many of the students felt they had spent enough time on clinical research that year and did not wish to have anything further to do with the study.

The author attempted to address this low rate of questionnaire return by inviting final year students to attend focus groups to discuss their research experience, however no students from the initial final year involved in DOOHS wished to attend focus groups. Therefore the results of the post study student questionnaires cannot be taken as representing the complete student view, it is likely that only students holding strong views or interested in clinical research returned their questionnaires.

Students returning the questionnaires inflated their involvement in the study, with individual students reporting to have recruited more patients to the study than the DOOHS records reflected. All students returning the questionnaire reported to have had some involvement in the clinical research process even if it were just handing out the patient information packs. The 36 students returning the questionnaire reported to have returned a total of 432 patient information packs between them.

The student's reported views on carrying out clinical research may have been influenced by the negative feelings of the year group as a whole towards this particular study. The reported comments reflected these views somewhat and were not always completely factual.

Students reported that carrying out clinical research was, to some degree, stressful. Their comments indicated that this was due to a lack of time to carry out clinical research (8) and additionally deliver dental care within the same appointment (1), reporting that they only sometimes managed to carry out dental care and clinical research at the same appointment. Students reported finding DOOHS disruptive to patient appointments, strongly disagreeing that during the study there was minimal disruption to patient appointments. Future studies in dental outreach should factor in an additional appointment for the recruiting stage. This would take pressure off dental students trying to carry out clinical research and deliver dental care (especially advanced restorative care) in the same appointment.

Students also reported that the outreach supervisors were not always supportive towards the study and this perhaps added to their stress. The timing of clinical research, within the final year, was not considered to be a good choice. Students reported that their final year is busy enough without adding in something new. The parts of the clinical research they reported to find the most difficult were completing the study paperwork (16) and recruiting participants (8). They reported that they often ran over time during the study. Some students felt out of their depth more than usual.

Part of the problem with the recruitment of participants was thought to be due to the outreach attachment timetable. As students at that time were sent on week long attachments in two of the outreach centres and day attachments in the others there was little continuity of care. This resulted in students being dependent on the previous student having given out a study information pack. There was little control so that individual students could take to ensure that they recruited patients to the study. Few of the outreach centres were able to ensure continuity of care between individual students and outreach patients. There was an element of luck and altruism required in order to recruit a patient to the study. This was frustrating for students, only 9/36 of those returning the questionnaires reported to have recruited as many patients as they wanted to, and only 7/36 agreeing that they recruited as many patients as they were required to. Future studies in outreach could consider using

clinics which can organise continuity of care between outreach patients and final year students.

Slightly more students reported to find carrying out clinical research to be encouraging rather than embarrassing and easy rather than difficult. The majority did not feel clinical research was something they should carry out as dental students. This would indicate that a change in mind-set is required in order that students feel clinical research is something that they should do as dental students. Perhaps more information on primary care research projects which are carried out currently in dental practices, more discussion about clinical research throughout the curriculum and funding which is available for clinical research studies could be beneficial in changing their mind-set. Students need to feel that research is something which is achievable, normal and that will be rewarded in dental practice. Students reported that they '*just want to be dentists*', they do not see clinical research as something dentists 'do'.

With this study in particular, the majority of students reported that they coped with clinical research and that they delivered oral hygiene instruction and advice as required to their patients. They reported to be confident in answering questions about the study and that they had all the information they required from researchers. Students had mixed views on their confidence carrying out study protocol and consent procedures. Their views were not reflected by the consent forms the author collected from the outreach clinics, which were, on the whole, very well completed. The study procedures the students struggled with were filling out all the different forms and log sheets. This was not helped by the different layout of each outreach clinics and their varying approaches to the clinical research organisation. Future studies in outreach would be advised to standardise the way the research paperwork is presented at the outreach centres. This study let each centre find their own way of managing the study. The centres where the students coped best and who recruited and retained the most participants were those where there was a member of staff who had taken sole responsibility for the study paperwork and who organised a specific research area for this. Organisation was improved further for students when there was continuity of staff and one particular staff member who worked in outreach the

majority of the week. These differences between outreach clinics explains the mixed response from the students on whether they were given all the help they required to follow the study protocol from outreach supervisors, and in completing the paperwork.

The students did report that they felt positive about being involved with the study. In particular they enjoyed interacting with the patients and involving the outreach patients in clinical research. They enjoyed the topic of prevention and considered it to be a good thing to be focussing on and relevant for outreach patients. They did not report that being involved in the study made them any more confident about delivering oral hygiene advice or demonstrating techniques. This could be because by final year they are already experienced at delivering preventive care. Students reported that being involved in research made them more confident in inviting patients to participate in clinical research studies and in following a research protocol. However their involvement had not made them confident in fitting in clinical research alongside usual dental care or in coping with a clinical research study. Students reported that it was important during clinical research studies in outreach that they have the ability to carry out patient treatments as well as clinical research at the same appointment. Students disagreed that their involvement in this study made them confident in starting their own clinical research projects. This was reflected in their free text responses around the volume of work involved in clinical research. Many of the students reported that their involvement had highlighted to them the large amount of work that goes into clinical research. Only two of the students reported clinical research in dental outreach to be enjoyable.

Students appreciated being given the opportunity of being involved in clinical research, even if they didn't enjoy it. They reported that their involvement had taught them new skills. Students reported that being involved gave them insight into the amount of work involved in clinical research and some reported that it may improve their career development and could be added to their CVs. They were mainly of the view that it was important their input could be recognised. At the time of completing the questionnaire the students overall disagreed that clinical research during dental outreach improved their future employment opportunities. The

majority indicated that they did not intend to take part in clinical research in the future. The student comments around CV enhancement and future career development were substantiated two years later, when some of the students who had been involved with DOOHS were applying for post-graduate clinical trainee positions and had referenced their involvement in DOOHS on their application forms. Their involvement in clinical research awarded them additional points in the selection process for interview.

When questioned about how pressured they felt to carry out clinical research, the students reported that most of the pressure to carry out clinical research came from researchers and the least from outreach patients. They also reported that they are most motivated to do what patients and dental supervisors/consultants think they should. This explains the lack of motivation of the students towards the study. The majority of students disagreed that the outreach staff were enthusiastic towards the study and they reported that it was very important to them that outreach staff were enthusiastic. The attitude of some staff would have made it more difficult for the students to feel enthused about clinical research in dental outreach. Students reported that they usually asked their colleagues and/or the dental outreach nurses for help if required as opposed to contacting the research team.

Students reported that in dental outreach research studies it was important to them that the topic was relevant to outreach patients, and that they had easy to follow instructions. Overall students were neutral on whether dental undergraduates should have the opportunity to carry out clinical research during outreach placements and mixed on whether they could achieve the skills to carry out clinical research on outreach placements. They held mixed views as to whether the outreach clinics are a good research environment. They did agree that taking part in clinical research should be part of the undergraduate curriculum.

9.2 Post-Study Student Focus Groups

Although there was a low rate of return of the post-study dental student questionnaires, these identified areas requiring further investigation in order to fully

explore the delivery of clinical research studies in dental outreach. Student focus groups were considered the most appropriate method of fully exploring the areas in question. Focus groups allowed the generation of richer data, providing further insight into the student views. Focus groups additionally afforded the students further opportunity to engage with the research process and discuss their first-hand experiences collaborating with the clinical research study.

The initial (recruiting) year group of students all declined the invitation to attend focus groups. This may in part have been due to the timing of the focus groups; after their finals examinations when they had finished their dental degree and were busy with graduation preparations.

As the initial group of students had declined the invitation to attend focus groups, the following year group of students involved in reviewing DOOHS participants were invited to attend focus groups. Although not involved in participant recruitment, this year group had been responsible for carrying out the review visits for DOOHS participants and were willing to attend the groups.

9.2.1 Post-Study Student Focus Group Objectives

The objectives of the focus groups were:

- to explore dental student views towards conducting clinical research studies in outreach clinics
- to explore barriers to and facilitators towards the conduction of clinical research studies in outreach clinics by dental students
- to inform future studies in outreach.

9.2.2 Post-Study Final Year Student Focus Group Methodology

Dental students who had attended dental outreach clinics during June or August 2011 while DOOHS review visits were underway were invited to collaborate in focus groups. These students had potentially reviewed participants of DOOHS. The invitation to the students explained the aims of the focus groups and stressed that they were to be conducted by an independent researcher with no ties to the dental degree. Refreshments were also offered during the focus groups.

An independent researcher conducted the groups to allow the students to freely discuss their experience of clinical research in dental outreach. The groups were voluntary and formed part of DOOHS for which ethical approval had been granted.

Dental students wishing to discuss their views attended one of two sessions. Each group consisted of around eight students. At the beginning of each session students were assured of their confidentiality and no register was taken. There was a break after 45 minutes within each session where the students were given refreshments.

9.2.2.1 Questions for Discussion

Questions for discussion by the students were categorised as follows:

- General questions regarding their views on students carrying out clinical research in outreach; their perceived advantages and disadvantages of clinical research in outreach for the groups involved (students, staff and outreach patients) and how they felt about taking part in DOOHS was also asked.
- Questions on the training and preparation which they had received, how it could have been improved and who they approached for help during the study
- Specific questions about their experiences in carrying out DOOHS
- Their views on research in general and in relation to the undergraduate curriculum.

The questions were used to guide the students' discussion. The student discussion was very much driven by their views of clinical research and their experiences during DOOHS.

The discussion was recorded with the students' permissions and subsequently transcribed maintaining the anonymity of the students.

9.2.3 Post-Study Student Focus Groups Methodology of Analysis

Thematic analysis (as discussed in Section 4.1.3) was carried out on the transcripts by two independent researchers including the author. These transcripts were analysed individually for common themes. It was identified that the two groups had similar views and responses. Therefore these findings were merged for presentation and discussion purposes.

9.2.4 Post-Study Final Year Student Focus Groups Findings

Overall, the students were of the view that carrying out clinical research in dental outreach would be of benefit to them, however the student discussion highlighted many negative views the students held towards this particular research study which they collaborated with during their time in outreach. It should be noted that the year group of students who took part in the focus groups may have been influenced by the previous year group of dental students.

Finding 1 - Clinical Research in Dental Outreach should be optional

The students were of the view that clinical research in dental outreach clinics should be optional. The students really disliked the compulsory nature of DOOHS.

“It puts you off in a way, if you get forced into doing something.”

Students discussed their view that if this particular study had been optional that the majority of students would have collaborated anyway.

“I think if it was optional then at least 95% of students would have done it anyway.”

This however is only the opinion only of one dental student. There is no evidence that if items such as clinical research are made optional on the curriculum that indeed any students will collaborate. Only a handful of students take up the opportunity to carry out a BMSc after their second year for example. Collaboration with DOOHS had to be compulsory for the second year group of students as the outreach patients had already been enrolled in the study and if a participant was due a review appointment, the examining student had to carry out the measurements required. Students cannot refuse to carry out dental treatment that patients are booked for on outreach clinics.

Finding 2 - Clinical research in dental outreach should be sold as an opportunity

Students were of the view that this project could have been ‘sold’ to them better and presented as more of an opportunity. They resented that they had no option but to collaborate with the clinical research study – there was no opt-out. Students were of the view that this approach was off putting for them.

“The way it was put...a slave rather than a valued member of it.”

“It puts you off in a way, when you are forced into doing something.”

At the time of the study the students involved did not express this view that they felt there were ‘slaves’. They were collaborates in the research. If they had expressed this view at the time of the study such misconceptions could have been addressed.

The fact that this particular study was linked to a PhD made the students resent the research further; they felt that they were being used for another’s gain.

“I still feel a little bit that I’m doing her PhD for her.”

Students additionally indicated that their negative feelings had been directly influenced by the previous year group of students and that this was perpetuated by some of the outreach supervisors.

Finding 3 - Dental Outreach was considered to be a good environment for clinical research

“People aren’t paying for their treatment and are less likely to have good oral hygiene”

“Good demographic and good range”

“It’s a good place to do research”

“Quite a good place”

“Good way of getting a wide number of people in the study”

“University can provide training”

“Useful opportunities to take forth into another study”

“You can actually do this thing again, hopefully”

“Outreach could be an amazing opportunity for research if done correctly”

“Good opportunities with the extra-long appointment times...”

“Really good place to do research...encourage people to do it in practice”

“I don’t see it as a research project, I see it as an opportunity to learn more about oral hygiene”

“Advice about communication skills, further enforcing what you have learnt before”

“Long appointments in outreach”

The dental students were positive about dental outreach as a research environment. The links with the University were seen as providing opportunities for training and by having clinical research in dental outreach the students considered that it demonstrated to them that it could be carried out in general practice. They also cited the long appointment times in outreach as being of benefit to clinical research studies and that the patients had good variety of demographics due to the many outreach clinics.

Finding 4 - Students would prefer to be involved earlier in the research process

The students considered the timing and continuity of the study within the dental curriculum to be poor, they felt could not get the most out of the research experience due to the lack of continuity when it came to carrying out study procedures. The lack of involvement from the outset of DOOHS was also an issue raised.

The students identified that being brought in to carry out the reviews was not, in their opinion, ideal. They were of the view that they would have preferred to be involved from the start, including the choice of subject and design stages of research. They wished to feel more a part of the study, more than just carrying out measurements and being involved from the very start would have been one method of addressing this.

The students disliked only being involved in one part of the study and wished for more continuity:

“Would have liked to have been more involved in the study, not just reviewing”

“We’ll need to get involved much earlier on in that process (of designing the research project)”

“If we’d seen it from the start then it might have been a bit more interesting”

“I think it would’ve been more interesting for us or we’d have felt more involved if we’d seen the patients since day zero... I think we would’ve felt more of a part of it rather than being given this little bit”

“So you’ve got this trial that’s ready to go, whereas even if you are thinking of going into research it might be more useful if you’ve seen it from the idea”

The timing of outreach (within the final year only of the dental curriculum) resulted in dental students only being involved with part of this particular study. If the study had had a shorter recall, it may have been possible to have students recruiting participants and reviewing within the same academic year.

Finding 5 - Future studies in outreach should carefully assess training needs of student researchers

The theme of training was brought up by both focus groups. Both student focus groups were in agreement with their view that training was too long. They were of the view that the training (although reduced substantially from that received by the first cohort of dental students), was still too involved with too much information delivered. They did not find the method of delivery stimulating enough.

“everyone was switching off” (FG1)

They did not see the point of the GCP components and although this had been reduced after feedback from the previous final year from the initial year’s 3hrs down

to 45 minutes, the students still regarded this as too long. Yet, in a contrary way, they still wished for more information. The way research was delivered within the dental curriculum was highlighted as an area to be addressed. The key may therefore be in delivery of smaller packages of information through group tutorials, leading up to a clinical study. This would however require much coordination and would be better delivered earlier in the curriculum due to timetabling.

Finding 6 - Study protocol needs to be conveyed in a clearer way to students

Although many viewed training to be too long, there were student comments which suggested a misunderstanding of a number of key points about the study and that an opportunity to educate them around research methodology had been missed. The students were of the view that this study had the potential to cause harm to patients which was obviously not the case, or it would not have gained ethical approval.

“If a patient was in the control group, you could see that there was just plaque everywhere and it was causing damage”

Students however had no idea which group the patients were in and in any case did not appreciate that patients could easily be removed from the study if necessary. Others had understood the point that participants could be withdrawn:

“Never really our decision (to withdraw a patient), because if you wanted to withdraw the person then you had to go speak to the supervisor.....and they would make the final call.”

The students did not understand why they didn't require calibration as researchers taking measures and considered this to be a disadvantage of studies in outreach.

The timing of training was considered to be more favourable for the first group of students, who attended their outreach attachments in June. The group who attended outreach in August had also received their training in April. Their time between

training and physically reviewing a DOOHS participant was considered to be too long. Students felt that the timing of the training was a barrier towards their delivering research in outreach.

The lack of information about, and involvement in DOOHS prior to their final year, added to the confusion. Although they felt the research training took too long they still remained confused about why the study methods were designed in a particular way. The training, although ticking GCP requirements and delivering enough information to enable students to navigate paperwork and carry out study procedures, obviously did not actually address the needs of the students. Students needed to know why DOOHS methods were set up a particular way. They were confused about the research design. This possibly resulted in students losing their confidence in this particular study's value.

Finding 7 - The final year is not considered the best place to start clinical research

Students were of the view that if clinical research is to be included in the curriculum that this should be earlier, not 'thrown in' as an add-on to the final year. The students' attitude towards research may have suffered from the study being 'thrown' into the already busy final year with very little introduction. The students did not see the connection between their involvement on a clinical research study in the final year and their research module 'Dental Informatics' which they completed in their second year. This timing could be improved to ensure that there is a direct connection between research components of the dental curriculum through spiral integration. Unfortunately, as it stood, one student was of the dismal view that the clinical research was:

"... just another thing on top of a difficult and challenging year"

In the final year students are maximising their dental experience: they value complex dental procedures over clinical research.

"Thought it (DOOHS) was eating into clinic time"

“5th year you probably have enough on your plate”

“Missing out on skills because of the subject”

Outreach reports (Watt 2010,2012, 2014) for the year the students carried out the clinical research study showed an increase in total procedures carried out during the year compared to previous years. The student’s view that they were missing out on skills due to the research project was therefore not substantiated. Misconceptions in student understanding of DOOHS became apparent during the focus groups.

“...and you'd know what group they were in so you might kind of bias your recordings” – There was no way that the students could know which group the participant was in.

“We hadn't obviously been calibrated against each other” – The methodology was not clearly conveyed.

“No doubt that the patient is disadvantaged (over not getting additional OHI)” – Misconception about how ethical approval works.

“The validity would be much improved if you could see the patient from day one...the readings would mean a lot more” – Research methodology misunderstanding.

Perhaps if students had been more confident in their study methods and in the study itself they would have been more engaged with it.

Finding 8 - Students considered that continuity of care was a barrier towards clinical research in dental outreach

The clinics were discussed by both student focus groups. Students rotate round the different outreach clinics so students attending the groups had an insight into the barriers in more than one outreach area.

The lack of continuity between the outreach clinics was cited as a barrier to clinical research in dental outreach. The outreach clinics were each set up differently and each managed the study in their own way, this was noted by the students and resulted in stress for them as they could not find what they needed in an unfamiliar clinic. This proved to be a barrier towards their engagement with the clinical study.

“Some of us didn't know where it all was”

“That was the only one (the only clinic where the nurse got things ready)...the other place you had to find everything for yourself”

“Paperwork needs to be easier to locate within the clinics”

“I don't think Aberdeen was that good... you had to get everything yourself”

“I had my first one in Aberdeen and I didn't have a clue where anything was”

“I had to do all of that myself”

Each outreach clinic had different appointment expectations for the students and getting the balance right between clinical research and practical dentistry was seen to be a challenge at some clinics, whereas others had organised the appointments so that there was time for the study and paperwork. This was recognised by the students:

“Improvements in the appointments (adding on time for e.g. for the study)”

“Actually been booked in at the wrong time my whole morning was doing nothing because the patient had to get put back another month”

Finding 9 - The support from outreach staff was variable

The staff were seen as a barrier in some of the clinics. Students were of the view that some staff were open in their views that clinical research not being of equal importance to providing dental care, and as such it was pushed to the end of the appointment which could have affected the measures taken. The attitude from the students was that the study was:

“Extra to do at the end of the appointment”

The students considered outreach staff in some of the centres to be unsupportive and unenthusiastic.

The students did identify that the outreach staff had the potential to facilitate clinical research in dental outreach. They highlighted staff in some outreach clinics as helpful. The research was facilitated by staff identifying to the students when a patient was involved in the study so they were aware and knew what to do.

“In Cupar, advisors would look through your paper notes every day to see what you had and so they would maybe point out that 'oh you have the study today'”.

The students were unanimous in their view that the outreach nurses were the biggest facilitator for clinical research in dental outreach.

“Yeah it was made really easy by the dental nurses.”

“Where I was they knew exactly where everything was, they said where to start, what to do and it took about 5 mins.”

“They were giving them the questionnaire when they were in the waiting room.”

Other comments from the students included that the head nurses were “*completely switched on*” at some outreach clinics. Students were of the view that the key to clinical research in dental outreach working was the head nurses. They acknowledged that if they knew that there was a head nurse trained up on site then they would have felt comfortable going to them for help with the study.

Finding 10 - Patients viewed as facilitators to conducting clinical research in dental outreach

The student groups identified that outreach patients had dental disease and this was beneficial for research purposes. They also identified that outreach patients display a range of demographics and do not pay for their treatment. The students felt this was also beneficial towards clinical research.

Students reported outreach patients were happy to attend for research appointments, although these appointments usually included providing treatment for patients at the same time.

'Everyone seemed happy enough they were just getting on with it and they were getting their toothbrush every time'

It ‘heartened’ the students that patients would attend just for the study in some cases, though other patients who had travelled some distance to attend, wished treatment to be combined with the appointment. The students did also report that some patients did not remember they were doing the study or hadn’t understood various aspects such as having to complete a questionnaire each visit.

“Patients didn't always know what they were coming in for”

Even so, the students were of the view that the outreach patients were happy to participate in clinical research.

9.2.5 Post-Study Student Focus Group Discussion

The students took advantage of the opportunity to speak to the independent researcher and spoke openly about their experiences with DOOHS during the session they discussed how they had felt during the clinical research and their dislike regarding the research links to the author's thesis. The students had a number of recommendations based on their experiences and a good insight of the student experience of clinical research in dental outreach was obtained.

Students firstly felt they would have benefited if the training had been closer to the actual time they would be reviewing participants for the study. The timing of this was close for the first group to attend outreach but the second group found it difficult. Timetabling issues and the spread out nature of the outreach clinics prevented training being run alongside outreach attachments. The overall research training for this study did not serve the needs of the dental students.

The paperwork for the study was identified as confusing and the students were also left confused about aspects of the protocol. Confusion over the protocol led to student concerns over when oral hygiene instruction could be reinforced and concerns about removing patients from the study. They were also concerned about items such as calibration and blinding which could have been addressed in a basic research information tutorial. These smaller details it seems were lost in the requirement to cover GCP and the study in a short lecture. Although help sheets were available at the clinics they were not always to hand or used. If their involvement in the clinical study had formed part of research teaching built within the dental curriculum many of their concerns may have been addressed. In addition, this would have placed the study into context for them which may have helped their enthusiasm. Students did like the use of media in the form of the training video which was posted on the university website, having more web-based information should be considered for any future studies in outreach. No doubt many of the student concerns did not come up until they started seeing study participants, so maybe a catch up session at the end of their first week in outreach would have been helpful. This could have been done on a web based format such as Skype, to allow

students to call in from the different clinics with their questions and discuss their experiences and concerns early on. Unfortunately, none of the students contacted the research team with questions regarding the protocol. These items could now be addressed from the start in any future research studies in outreach.

Students wished to be more involved with the study. They felt they would have gained more if they had also been the recruiting researchers. They wished to be involved in the study design, and wanted to feel more part of things. For this particular project this was not possible due to timing issues around the student year and start of the study. However, with careful planning, it may be possible to arrange a study which could be followed through by the same group of students by having a shorter review time.

The students reported outreach patients were happy to attend for research appointments, although these were usually providing treatment for patients at the same time. Students did also report that some patients did not remember they were doing the study or hadn't understood various aspects such as having to complete a questionnaire each visit. Students recognised that the questionnaire also caused difficulty for some patients who had forgotten their glasses or didn't understand questions. Simplification of any future studies in outreach would be recommended as would the initial piloting of any future questionnaires with a group of outreach patients. The questionnaire used in this study had previously been used in general dental practice and in hindsight was too long and wordy for the outreach clinic environment. The patients seen in outreach are not the regular attenders of general dental practice which this questionnaire was previously validated for.

The students felt that outreach patients had much to bring to this research: patients often displayed poor oral hygiene, exhibited a good range of demographics, and didn't pay for their treatment. Although the patients had poor oral hygiene, the students thought that oral hygiene wasn't the best subject for research. There was concern that patients were disadvantaged by not receiving OH at every appointment although anecdotal, personal experience would suggest that students do not normally give oral hygiene instruction at every appointment. Student training could have been

improved to allow better understanding of the protocol with respect to this. Students reported confusion among outreach patients as to what their research appointments were for. It may be worthwhile in future studies to make a specific appointment card for the study appointments so the patients can identify the reason for attendance. This study used the computer programme utilised in outreach clinics to identify the participants of the study. However, this was not very successful as the study icon on the R4 screen was not easy to see unless the student was looking for it so it was easily missed by students.

There were no patient complaints to the research team during the study regarding the care they received at the study appointments when the study measurements were carried out. Two of the outreach patients remarked on their questionnaires that they had attended appointments but the measurements had not been taken by the student. They were disappointed that their research involvement had been missed.

The students felt disadvantaged by the organisation of the study materials which varied from clinic to clinic. Kings Cross and Kirkcaldy were recognised by the students as the best organised outreach clinics. At these clinics the head nurse or senior outreach staff sorted all the materials for the student and took control of logging things so the student was told exactly what to do. At other clinics students were left to find materials for themselves. This proved to be another barrier to carrying out research efficiently. There was the occasional mistake by the outreach clinics in booking patients in at the wrong time but these were usually easily rectified. It was helpful that participant did not have to have continuity with students for the research. If the same students had been required to carry out measures each time, this would have been very difficult. Lack of continuity between the clinics was considered to be a problem. Students suggested that there should be a box where everything for the study was kept. In fact there was an area in each clinic where all the materials were kept. However, as this was not obvious to the students and the location of this varied from clinic to clinic, it was often missed. The attitudes of the staff were not consistent across clinics and often unhelpful. In fact, at one clinic, a student reported that the member of outreach staff was disparaging about the study while a participant was in the dental chair. Supervisors were

generally cited as not seeing research as a priority and unsupportive supervisors proved to be a barrier to research in outreach. This was unfortunate as in two of the outreach clinics the staff were running the study in a very efficient and organised manner.

Students felt outreach clinic organisation impacted on whether the review was carried out or not. The more chaotic the clinic was regarding turnover of staff the less likely the research would be completed and more likely that the patient would receive dental care only at the research appointment. In general though, the reviews were carried out when the participant attended.

Nursing staff were seen as key to getting research in outreach to work. Outreach sites where students found research easiest had key nursing staff taking control of the study paperwork and organising the review appointments.

Student Attitudes towards Research

The overwhelming opinion from the students was that research should be optional. They did wish it was better integrated into the course but from an earlier stage. Final year was considered too busy a year to introduce research. Students need to know more about research ongoing within the dental school and to be able to choose to sign up for involvement in ongoing projects. It was recognised that there are many aspects of the course which were not optional and that DOOHS didn't involve much over and above what they would be doing as dentists anyway. Students felt that introducing research into second year may be a way for those wishing to be involved with such a simple study as this one to get involved.

Students weren't enthusiastic about this particular study, as they felt it wasn't sold well to them. They were of the opinion that patients would not benefit. The topic wasn't of interest. This highlights the importance of research teaching early on in the undergraduate dental curriculum in order to address attitudes towards research and their general understanding (participants of research are not usually the people who will benefit).

Students did consider outreach to be a suitable place to carry out research due to close ties with the University (they can provide training for example) and the large number of people involved in outreach and the long appointment times.

Research in General

Students thought that this research was a good opportunity which had been sold badly. By making DOOHS involvement compulsory for students, it put them off. Research was seen as very important by the students but they identified that most of them 'just want to be dentists'. The students didn't think there would be time for research in their future careers unless it paid well or they wanted to pursue academia.

The Curriculum

The students identified that research was important within the curriculum and that timing of the study could help with selling it to students. It was suggested that it be run in as modules incorporated into the existing curriculum or made way for by removing some less current aspects of the curriculum. It was suggested that research could be part of their electives.

Leaving research to final year was not appreciated by the students and they felt if it was tackled earlier on then it would become a more integral part of dentistry instead of an add-on. Initially, they would prefer to receive basic information about simple things such as audit. They wished to be made more aware of the pathways within dentistry and what academic staff were doing within the dental school. They felt that they were unaware of what was going on and wished to be more involved. They suggested a symposium where the research-active staff could discuss what they were doing. This would make such staff more approachable to students who were keen to get involved with research. Compared to the medics, they felt disadvantaged in this area. The dental students perceived their medical equivalents as being research active although it was the dental students at Dundee University who were, in fact, the first students to carry out a clinical research study. They found it interesting and inspiring to see faculty involved in research activities but felt that they could not

directly approach staff and ask to be involved as they were unaware of exactly what everyone was doing.

9.2.6 Points from the Student Focus Groups to Inform Future Studies in Dental Outreach

To best facilitate clinical research in dental outreach the following recommendations came out of the student focus groups:

- Have collaboration in clinical research as optional, not compulsory for students
- “Sell” clinical research better to all parties
- Introduce research earlier in the dental curriculum
- Make research teaching part of the curriculum so that it is in context
- Time training to be as close to the start of research activities as possible
- Train outreach head nurses and enable them to facilitate the research at the clinics
- Work more closely with outreach nurses
- Make the appointments clearer for outreach patients and students, consider using a special colour of card or label
- Make the research projects short so students can follow them through to completion

9.3 Post-Study Outreach Staff Questionnaires

9.3.1 Post-Study Outreach Staff Questionnaire Objectives

The objectives of the post study staff questionnaire were:

- exploration of advantages and disadvantages of clinical research in dental outreach as perceived by outreach staff

- exploration of the barriers and facilitators towards clinical research in dental outreach as identified by outreach staff

9.3.2 Post-Study Outreach Staff Questionnaire Methodology

Paper questionnaires (Appendix 21) were distributed to outreach staff involved with DOOHS during the final patient review period. These questionnaires were distributed to the 29 staff who initially received training. Where possible, these staff were given the questionnaires by hand along with an envelope and a verbal request to complete and seal the questionnaire before returning it to the research collection box which was in each outreach centre. Where staff were not present at the time of the author's visit, the questionnaires were left in the outreach clinic in an envelope addressed to the staff member. The author collected completed anonymised questionnaires from the research collection boxes which were removed from the outreach centres at the completion of DOOHS.

The data from the staff questionnaires was inputted by the author and verified by an independent researcher not connected to the study.

9.3.3 Post-Study Outreach Staff Questionnaire Methodology of Analysis

Only a small number of questionnaires were returned. Therefore results were collated using excel and checked by an independent researcher. Detailed analysis was not indicated.

9.3.4 Post-Study Outreach Staff Questionnaire Findings

Of the 29 questionnaires distributed to staff who had received the initial training for DOOHS, 11 were returned to the author. These were completed by 7 outreach dentists and 4 nurses. As the return rate of the questionnaires was low (37.9%), detailed analysis was not indicated. The responses are outlined in Table 9.1.

Table 9.3: Staff post-study questionnaire responses

Question	Theme	Response		
1a	Before the study did you receive training about clinical research and the outreach study?	11 yes		
1b	Which aspect of the training did you find most useful?	Qualitative response see below		
2a	Overall as a supervisor did you receive	Qualitative response see below		
2b	If you were not given the correct amount of information how could things have been improved?	Qualitative response see below		
3	Did you find it easy to contact a member of the research team?	11 yes		
4	If you contacted a member of the research team were they helpful?	8 yes	3 N/A	
5a	I think students should be given opportunity to help decide research topic	7 agree	3 neutral	1 disagree
5b	I think students should be given opportunity to help decide study protocol	5 agree	4 neutral	2 disagree
5c	I think supervisors should be given opportunity to help decide research topic	10 agree	1 neutral	
5d	I think supervisors should be given opportunity to help decide study protocol	8 agree	3 neutral	
5e	I would be willing to participate in deciding the research topic	9 agree	1 neutral	1 agree
5f	I would be willing to participate in development of the study protocol	10 agree	1 neutral	
5g	I think students should have the opportunity to carry out a research study	10 agree	1 neutral	

Question	Theme	Response		
5h	I think supervisors should have the opportunity to collaborate in a research study	10 agree	1 neutral	
6	Do you believe clinical studies can be carried out successfully in outreach?	7 yes	4 unsure	
7	Do you believe clinical studies should be carried out in outreach?	6 yes	5 unsure	
8a	In future dental outreach research studies how important is it that the research topic is relevant to outreach patients	11 important		
8b	In future dental outreach research studies how important is it that the study protocol is easy to administer	11 important		
8c	In future dental outreach research studies how important is it that any disruption to dental outreach is minimised	11 important		
8d	In future dental outreach research studies how important is it that research training is CPD accredited	11 important		
9a	I believe that during the trial the students often carried out clinical research and patient treatment at the same time	7 agree	1 neutral	3 disagree
9b	I believe that during the trial the students often carried out examinations/radiographs or treatment planning and clinical research at the same time	8 agree	1 neutral	2 disagree
9c	I believe that during the trial the students often carried out fillings and/or periodontal treatment and clinical research	5 agree	2 neutral	4 disagree
9d	I believe that during the trial the students often carried out extractions or denture work and clinical research	5 agree	1 neutral	5 disagree

Question	Theme	Response		
9e	I believe that during the trial the students often carried out complex treatments such as endo or crown work and clinical research	2 agree		9 disagree
10a	It was easy to follow the protocol	10 agree		1 disagree
10b	There was minimal disruption to patient appointments	6 agree		5 disagree
10c	Patients were keen to take part	5 agree	2 neutral	4 disagree
10d	The clinics were more stressful to supervise than usual	6 agree	1 neutral	4 disagree
10e	I required support in managing student activities more so than usual	6 agree		5 disagree
10f	The students needed more support than usual	6 agree	1 neutral	4 disagree
10g	The clinic was more challenging to supervise	8 agree		3 disagree
10h	I felt confident in what the students were supposed to do	7 agree		4 disagree
10i	The students were enthusiastic	1 agree	2 neutral	8 disagree
10j	The students took accurate measurements	5 agree	4 neutral	2 disagree
10k	The students delivered OHI appropriately	6 agree	5 neutral	
11a	Supervising clinical research in outreach was enjoyable for me	7 agree	2 neutral	2 disagree
11b	Supervising clinical research in outreach has helped my career	4 agree	4 neutral	3 disagree
11c	Supervising clinical research in outreach taught me new skills	5 agree	3 neutral	3 disagree
11d	Supervising clinical research in outreach was confusing	2 agree	2 neutral	7 disagree

Question	Theme	Response		
11e	Supervising clinical research in outreach was stressful	4 agree	2 neutral	5 disagree
11f	Supervising clinical research in outreach improved my understanding of research	5 agree	3 neutral	3 disagree
11g	Supervising clinical research in outreach was of benefit to me	4 agree	2 neutral	5 disagree
11h	Supervising clinical research in outreach improved my job satisfaction	2 agree	6 neutral	3 disagree
12a	I believe dental undergraduates should have the opportunity to carry out clinical research during outreach	7 agree	1 neutral	3 disagree
12b	I believe dental undergraduates can achieve skills required to carry out clinical research during outreach placements	7 agree	3 neutral	1 disagree
12c	I intend to take part in clinical research in the future	8 agree	3 neutral	
12d	I believe taking part in clinical research should be part of the undergraduate curriculum	6 agree	3 neutral	2 disagree
12e	I believe dental outreach clinics are a good research environment	6 agree	2 neutral	3 disagree
13a	Do you think your centre encountered any problems recruiting patients?	2 yes	9 no	
13b	Are there any ways patient recruitment could have been improved further?	(Qualitative response see below)		
14a	Are there any particular challenges you encountered during your supervision of the study?	(Qualitative response see below)		
14b	How did you overcome these?	(Qualitative response see below)		

Question	Theme	Response		
14c	Was there anything the research team could have helped you further with?	(Qualitative response see below)		
15a	Are there any aspects of the research that you found the students needed extra support with?	(Qualitative response see below)		
15b	What do you think would have improved this?	(Qualitative response see below)		
16	Are there any areas of the study you felt the students did particularly well?	(Qualitative response see below)		
17	What is your role in outreach?	7 dentist	4 nurse	

Key	
	Positive Majority Response
	Neutral Majority Response
	Negative Majority Response

Which aspects of the training did outreach staff find useful?

Three staff identified that the training video was the most useful aspect. Two staff mentioned the tutorial as useful and additionally the meeting with the author was considered helpful. One member of outreach staff identified that the Good Clinical Practice training was useful. The remaining staff either could not remember or did not answer the question. When questioned on how the training could be improved, it was identified that the training needed to be closer to the start of the study. It was thought that this would have helped with recruiting participants.

Were there any challenges in supervising the study, how could these have been addressed and could the research team have helped further?

One staff member identified that the students were difficult to motivate and lacked commitment. They were of the opinion that this could have been addressed by encouraging the students more and perhaps having a day in which to concentrate on recruitment. Staff were of the view that students needed better explanation of the benefits of taking part in clinical research.

One staff member explained that they had spent their own time during lunchtimes etc. phoning patients and sending letters out for the study in order to keep on top of the study appointment organisation. Organisation was identified as key to supervising clinical studies in outreach. This was seen by the author on clinic visits. The clinics which came across as organised to the author, had higher recruitment rates compared to the other outreach clinics.

One staff member was of the opinion that students were short of time to carry out patient treatment and that it was difficult to finish treatments alongside the study. They felt this could have been addressed through extra appointments. Another staff member was of the opinion that outreach patients were short of time and that the appointments are already long. They wished more information in advance about the length of time the study would take the students to carry out. At the time of the study, this was an unknown factor for everyone involved as students had not carried out clinical research in dental outreach before. Future studies in outreach could be better informed in this regard.

Were there any aspects of the research the students needed extra support for and what would have improved this?

Two of the outreach staff who completed the questionnaire identified that they needed extra support to address the lack of student motivation. They were of the view that the involvement of students earlier, at the protocol stage, may have helped

to address this. Staff also wished further help with the paperwork for the study and wished that the burden of paperwork to be reduced for future studies in outreach.

Were there any aspects of the study the students did particularly well?

Several staff were of the opinion that the students carried out oral hygiene instruction well during DOOHS: *'excellent OHI presentations', 'delivery of OHI very impressive'*. The students were also identified as being good at explaining the research to patients and at carrying out procedures once they knew what to do.

Other comments from the outreach staff included that the study had been: *'a huge learning curve'*, and that better *'buy-in'* from the students was required for future studies in outreach.

9.3.5 Post-Study Outreach Staff Questionnaire Discussion

The poor rate of return of the post-study staff questionnaires was thought to be due to the timing of the distribution. By the end of the study, many of the outreach clinics had seen staff move on so the staff trained at baseline were no longer available. There were also staff on holiday as the questionnaire distribution was during the summer period. This was especially evident in Inverness where the nursing staff had moved out of the outreach clinic onto other clinics and could no longer be contacted by the author. Where questionnaires had been left at clinics for staff, it was not possible to establish whether or not they had been received. It is very possible that staff who were most engaged with the study were the ones who returned their questionnaires to the research collection box. It is possible that some of the staff at the smaller clinics felt that although the questionnaires were anonymous that they would be able to be identified. This may have put some staff off returning questionnaires.

With hindsight, the outreach staff post study data views may have been better addressed through focus group work. This would have allowed further exploration of the outreach staff experiences during DOOHS and their views on clinical research

in dental outreach after their collaboration with a clinical study. However this would have only been possible during the annual outreach day as the rest of the time the outreach staff are teaching in the different centres.

Overall outreach staff were supportive of clinical research studies being carried out in undergraduate dental outreach clinics. They were almost unanimous that dental students should have the opportunity to carry out clinical research and that supervisors should have the opportunity to collaborate in clinical research studies. Staff were of the view that clinical research should be part of the undergraduate curriculum. They were of the overall view that clinical studies could and should be carried out in dental outreach. The questionnaires identified thoughts towards future studies in dental outreach.

Regarding set up of clinical research studies in dental outreach, staff were of the view that they, and the dental students, should be consulted on the research topic and were unanimous in their opinion that this topic should be relevant to outreach patients. They would be happy to be involved in the research topic choice and in developing the protocol. They were also of the view that students should be involved with the protocol development. Their involvement in the protocol stage may help with their next, unanimous, recommendation that clinical research studies should have a protocol which is easy to administer and that disruption to the outreach clinic is minimised. They also wished CPD for their involvement in the clinical research.

During DOOHS, supervisors were of the overall opinion that the protocol was easy to follow. On the topic of dental work being carried out alongside the clinical study, 8/11 supervisors reported that they believed the students were able to do this for simple tasks alongside the research. However, when it came to more complex treatments such as root canal treatment, 9/11 supervisors disagreed that such treatments could/should be carried out at the same time as clinical research. General restorative treatment delivery alongside clinical research was considered to be carried out by dental students by around half of the outreach supervisors.

Views were also split regarding the level of support required for the clinical study delivery. Half of the supervisors reported that they required more help on the clinics. Students were thought to require more support than usual when carrying out clinical research. The split views on this topic may be due to the set-up of the clinical research in each of the outreach clinics varying. Students reported that in some centres they could not find research materials. This would have resulted in them requiring further support to get organised for the patient's appointment. The clinics were considered to be more stressful to supervise by 6/11 supervisors, and more challenging to supervise by 8/11 supervisors.

Supervisors reported that students delivered OHI appropriately and took accurate measures during the clinical study, and that students could achieve the skills to carry out clinical research during outreach placements. They also held the general opinion that the students were not enthusiastic.

Supervising clinical research in dental outreach was viewed as enjoyable and, to some extent, supervisors identified that they had learnt new skills. The majority of supervisors did not report their experience to be stressful or confusing and that it helped their understanding of clinical research. 8/11 supervisors indicated that they intend to carry out clinical research in the future and that the dental clinics were overall considered to be a good research environment; 9/11 reported no problems in recruiting patients to the study.

On the topics of whether clinical research studies could be carried out successfully in outreach and whether they should be carried out in outreach, outreach supervisors were overall positive.

Overall, the supervisors who completed the post study questionnaires were positive regarding clinical studies in dental outreach with the main recommendations that in the future they wish to be consulted early to help with the development stage of any future studies in dental outreach and that it would be of benefit to dental students to have buy-in at the early stages of research development. It should be noted that those supervisors returning the questionnaire were likely to have an interest in

research or hold strong views on DOOHS. Ideally, a larger sample would have been collected or focus groups arranged. Neither of these options were possible due to time constraints and the geographical arrangement of the outreach clinics.

9.4 Post Study Outreach Participant Questionnaires

9.4.1 Post Study Outreach Participant Questionnaire Objectives

As previously discussed in Chapter 8, the participant questionnaire primarily measured reported oral hygiene behaviours. Additionally, this questionnaire fulfilled a second objective which was to measure outreach participant experiences of clinical research in dental outreach. A further objective was to afford outreach participant's the opportunity to respond to pre-study conceptions from dental students and stakeholders about their (patient's) priorities regarding time spent in the dental chair.

9.4.2 Post-Study Outreach Participant Questionnaires Methodology

The post study participant questionnaires were distributed at baseline and at the two review appointments (3 and 6 months). These questionnaires measured the reported oral health behaviours of the participants as discussed in Chapter 8. The questionnaires additionally asked participants their views on their experiences of DOOHS. The questions were designed to test i) the pre study views (Chapter 4) around the patient's expectations for their dental experience and ii) the direct experience of DOOHS. Additionally, there was a free text box which allowed further participant responses.

The following specific participant questions were posed:

i) Testing the pre study views of stakeholders, students and staff:

- It is important that the students take time with me
- It is important that I get my fillings done before anything else

- It is important that I get my gums treated before anything else
- It is important that my appointments are as short as possible
- It is important that the students get lots done so I don't have to come back as many times
- It is important that I receive preventive advice before anything else
- It is important that I have my usual treatment carried out as well as research at the appointment

These questions invited responses on a 7 point Likert scale ranging from 'Extremely important' to 'Not at all important', testing the pre study views that outreach patients 'just want to get things done' and the student view that they don't value prevention.

ii) Directly relating to their experience during DOOHS

- The students took time to explain things
- I had the opportunity to ask questions
- The supervisor checked the student's work
- The student was confident
- The student was enthusiastic
- The staff were enthusiastic
- The student explained things clearly
- It was easy to attend for this review appointment
- Overall the experience was interesting
- Overall the experience was enjoyable
- I would recommend participating to a friend
- I would participate in future studies in outreach

These questions invited responses on a 7 point Likert scale ranging from 'Strongly agree' to 'Strongly disagree'.

9.4.3 Post-Study Outreach Participant Questionnaires Methodology of Analysis

The questionnaire responses were analysed using SPSS for non-parametric analysis. Initially, the data was analysed for any differences between the intervention and control groups using Independent samples Mann-Whitney U Test at 0.05 level for questions tested once and corrected using Bonferroni's correction (Sedgewick 2014) for repeated measures (divided by 2 if the question was posed twice = 0.0025). Once it was established that there was no statistical significance between the control and intervention groups their data was treated as one dataset of views and the responses combined.

Table 9.4: Mann-Whitney U test results demonstrating control and intervention groups were not significantly different in their views

The distributions of the following questions were tested following the null hypothesis that there was no difference between control and intervention groups.	Time	
	T1= Baseline	Independent samples Mann-Whitney U Test Significance
	T2= 3 mth Review	
	T3= 6 mth Review	
It is important that the students take time with me	T1	0.666
	T2	0.495
	T3	0.815
It is important that I get my fillings done before anything else	T1	0.781
	T2	0.998
	T3	0.537
It is important that I get my gums treated before anything else	T1	0.555
	T2	0.816
	T3	0.677

The distributions of the following questions were tested following the null hypothesis that there was no difference between control and intervention groups.	Time	
	T1= Baseline	
	T2= 3 mth Review	
	T3= 6 mth Review	
It is important that my appointments are as short as possible	Independent samples Mann-Whitney U Test Significance	
	T1	0.797
	T2	0.971
It is important that the students get lots done so I don't have to come back as many times	T3	0.867
	T1	0.863
	T2	0.052
It is important that I receive preventive advice before anything else	T3	0.792
	T1	0.511
	T2	0.724
It is important that I have my usual treatment carried out as well as research at the appointment	T3	0.929
	T1	0.862
	T2	0.329
Do you intend to participate in the study?	T3	0.270
	T1	0.669
The students took time to explain things	T2	0.055
	T3	0.723
I had the opportunity to ask questions	T2	0.091
	T3	0.246
The supervisor checked the student's work	T2	0.193
	T3	0.105

The distributions of the following questions were tested following the null hypothesis that there was no difference between control and intervention groups.	Time	Independent samples Mann-Whitney U Test Significance
	T1= Baseline T2= 3 mth Review T3= 6 mth Review	
The student was confident	T2	0.213
	T3	0.056
The student was enthusiastic	T2	0.096
	T3	0.073
The staff were enthusiastic	T2	0.039*
The student explained things clearly	T3	0.229
	T2	0.409
It was easy to attend for this review appointment	T3	0.293
	T2	0.665
Overall the experience was interesting	T3	0.177
	T2	0.022*
Overall the experience was enjoyable	T3	0.444
	T2	0.073
I would recommend participating to a friend	T3	0.779
	T2	0.400
	T3	0.602
I would participate in future studies in outreach	T3	0.216
*Null hypothesis rejected at 0.05		

9.4.4 Post-Study Outreach Participant Questionnaire Findings

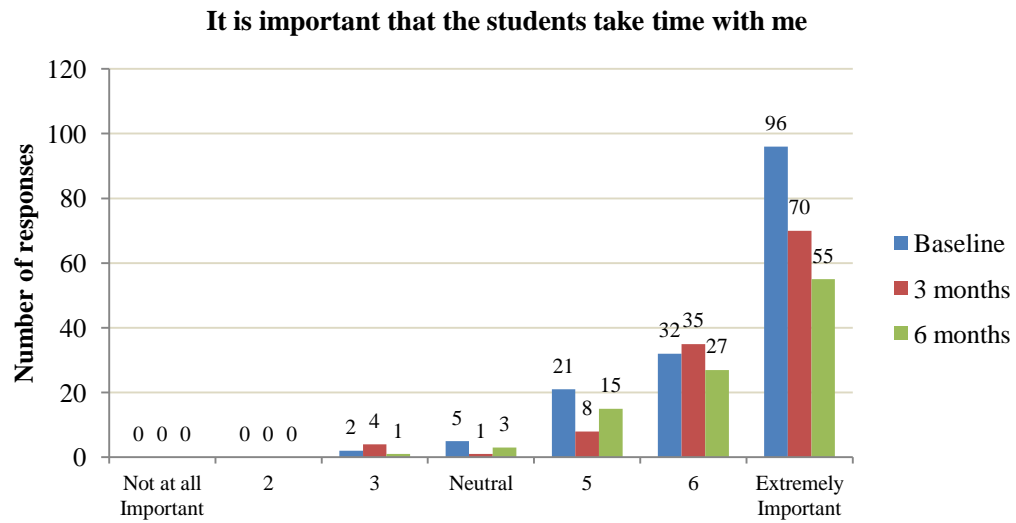


Figure 9.15 Post-Study Outreach Participant Questionnaire Findings

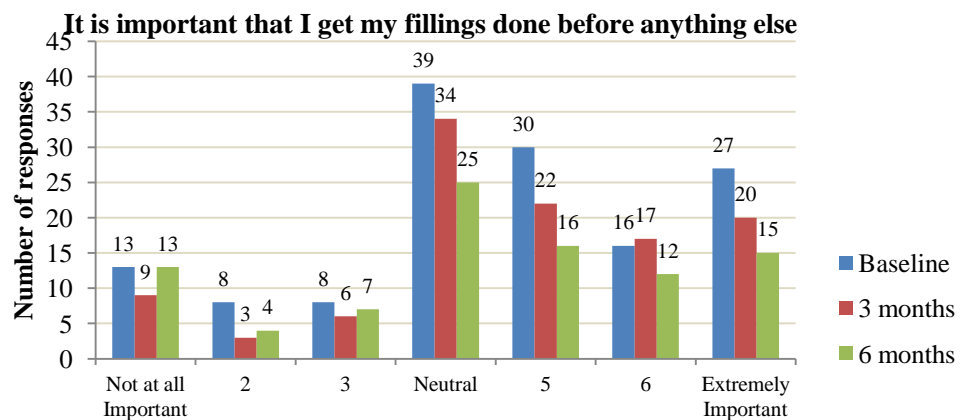


Figure 9.15 continued

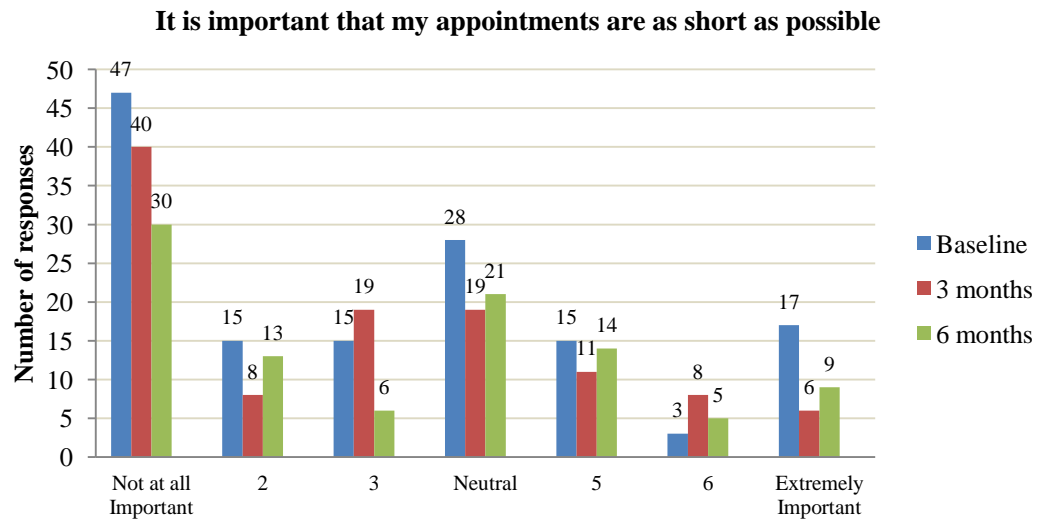
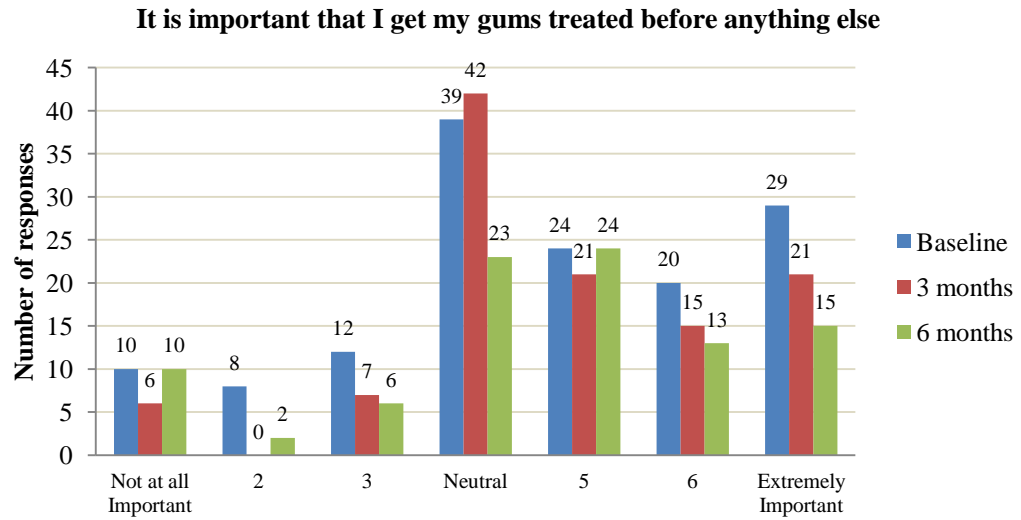
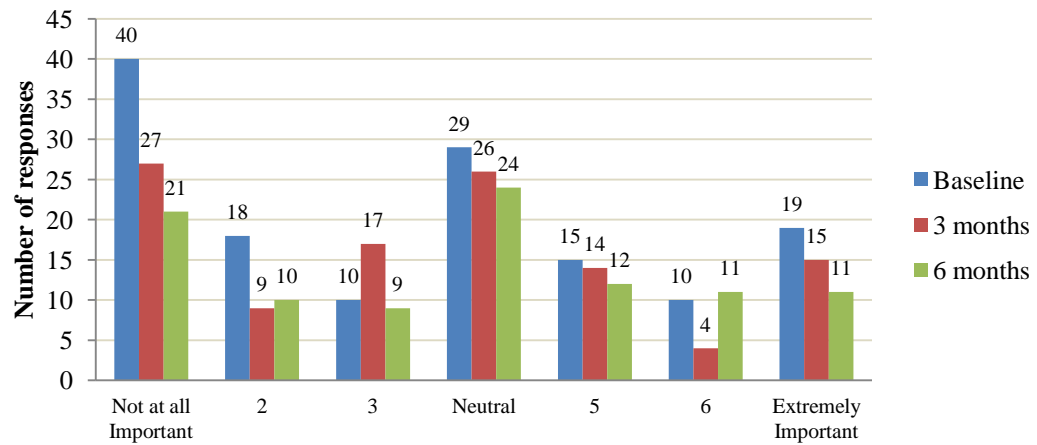


Figure 9.15 continued

It is important that the students get lots done so I don't have to come back as many times



It is important that I receive preventive advice before anything else

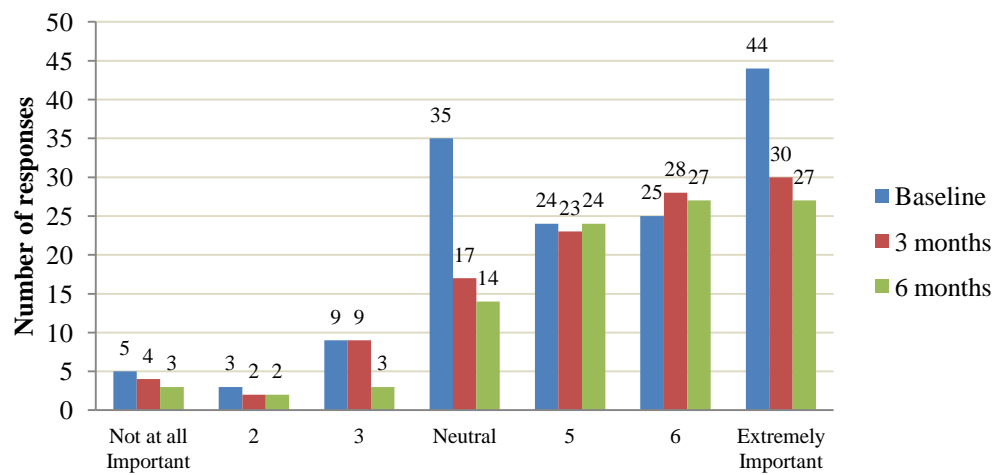
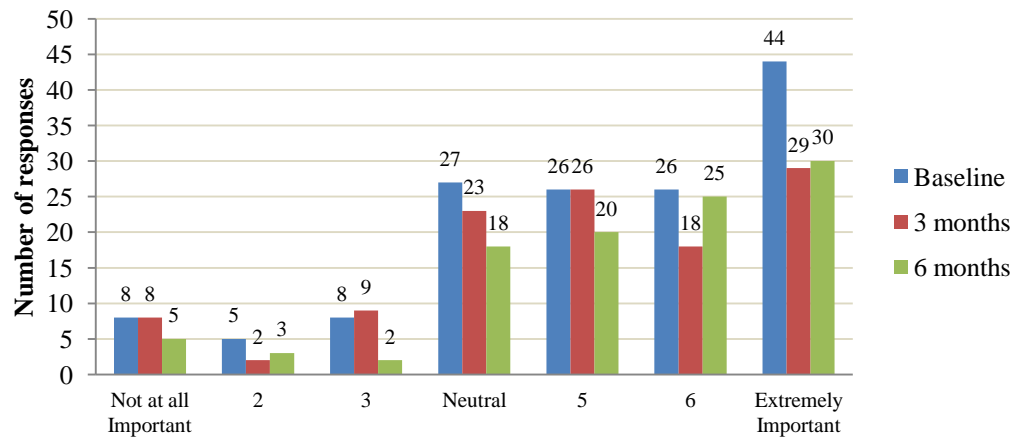


Figure 9.15 continued

It is important that I have my usual treatment carried out as well as research at the appointment



Do you intend to participate in the study?

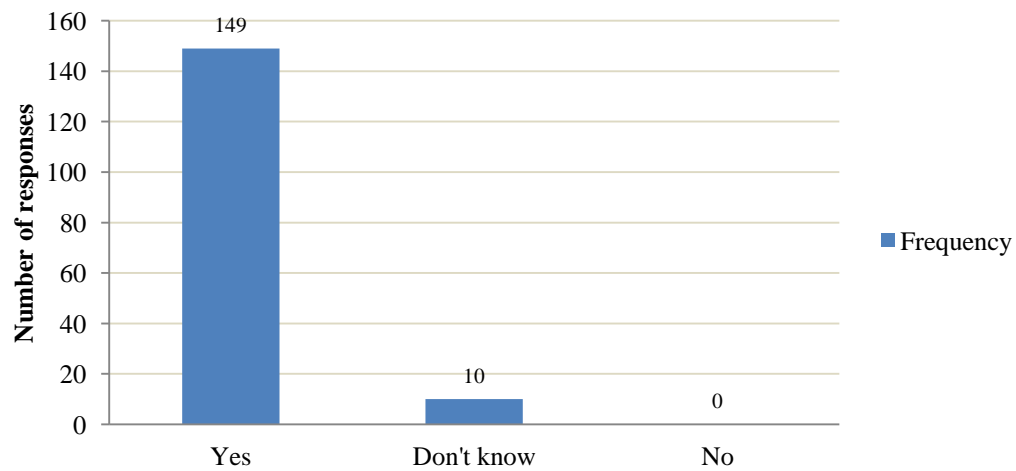


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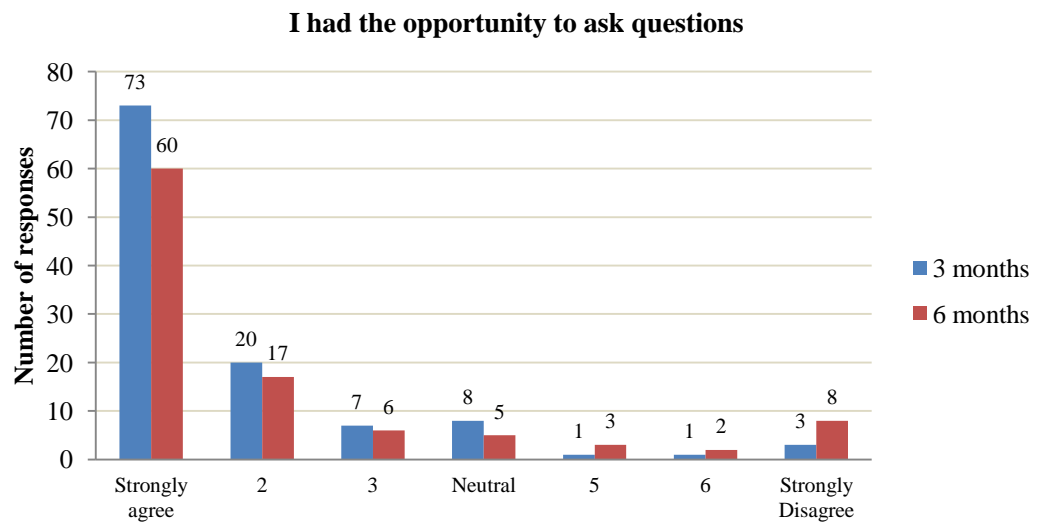
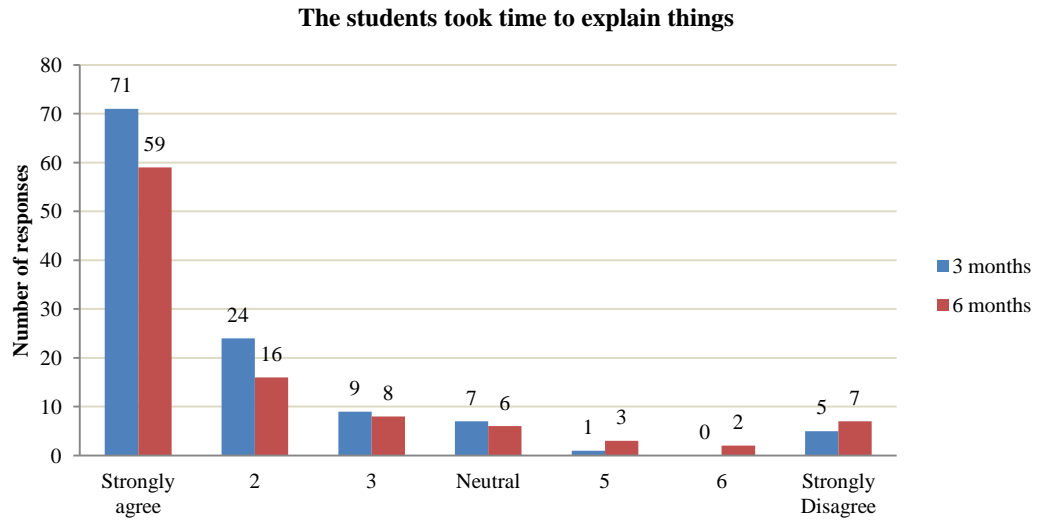


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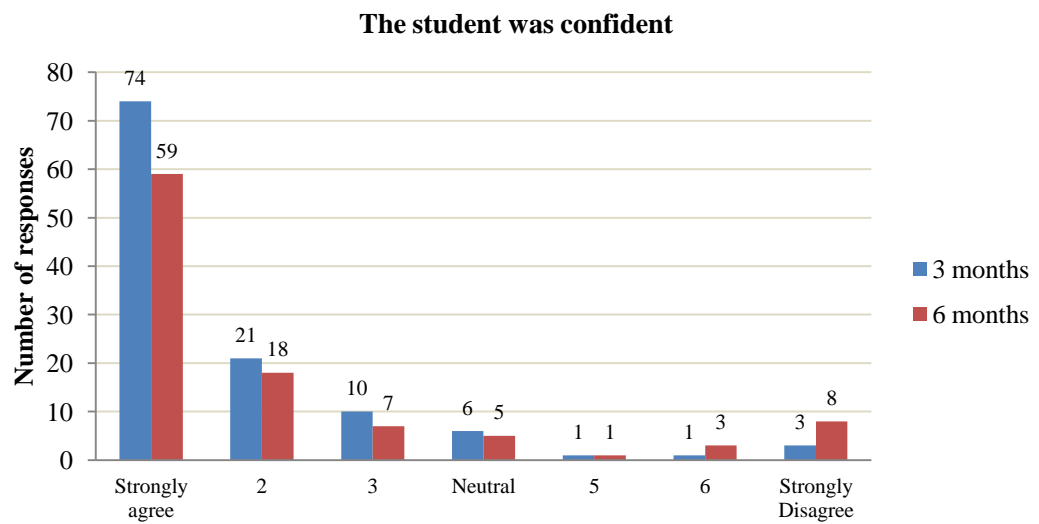
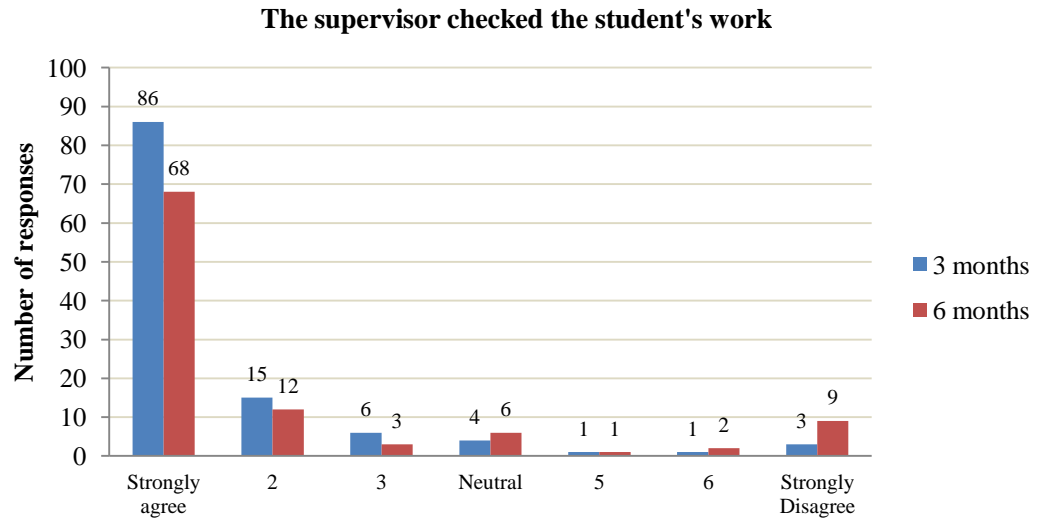


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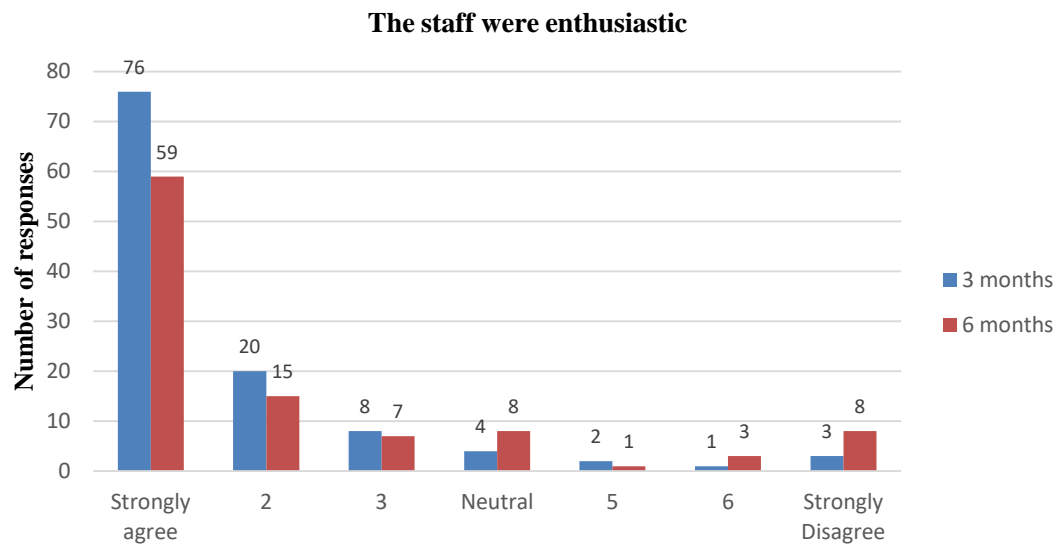
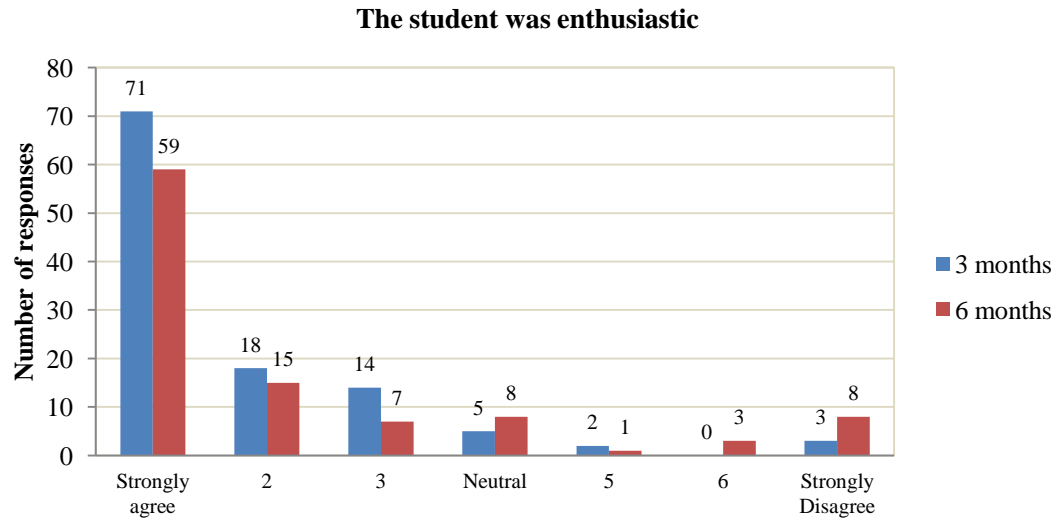


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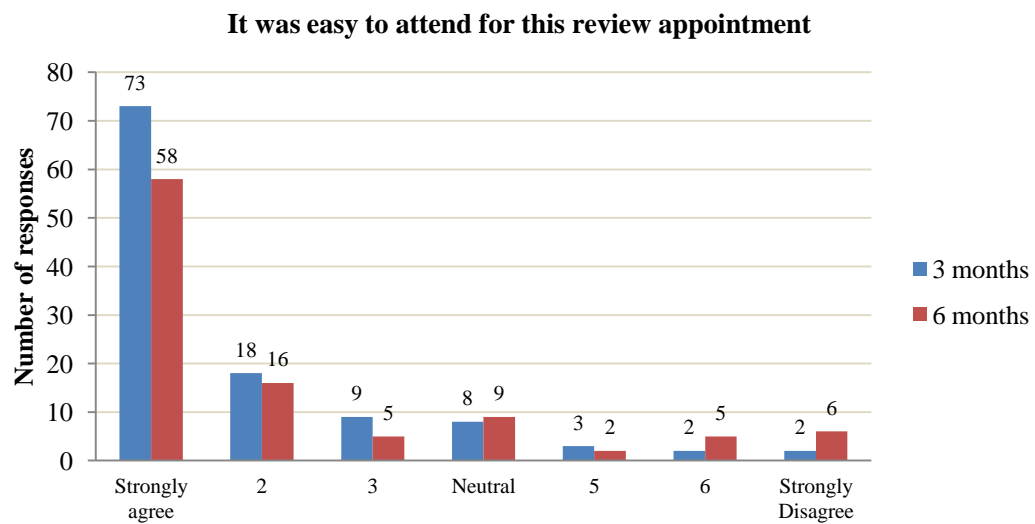
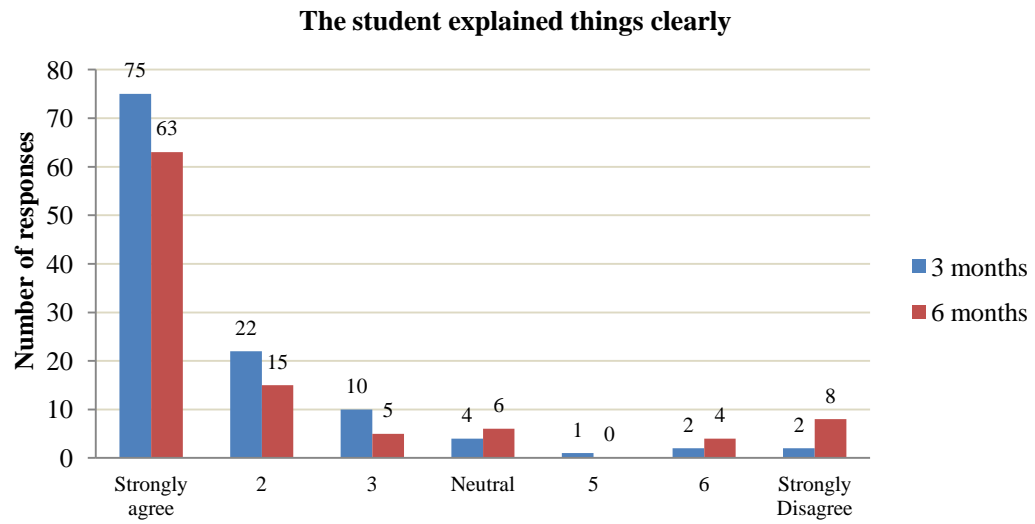


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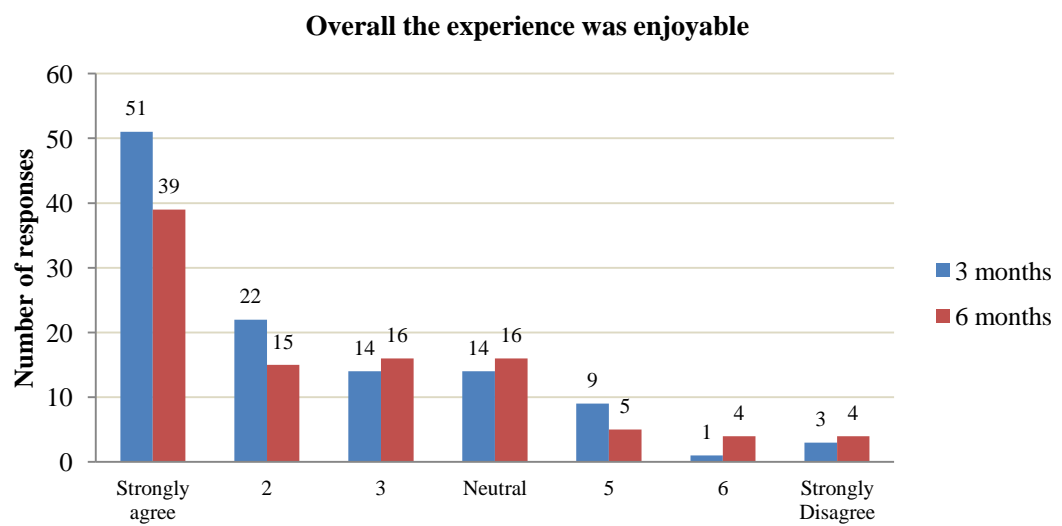
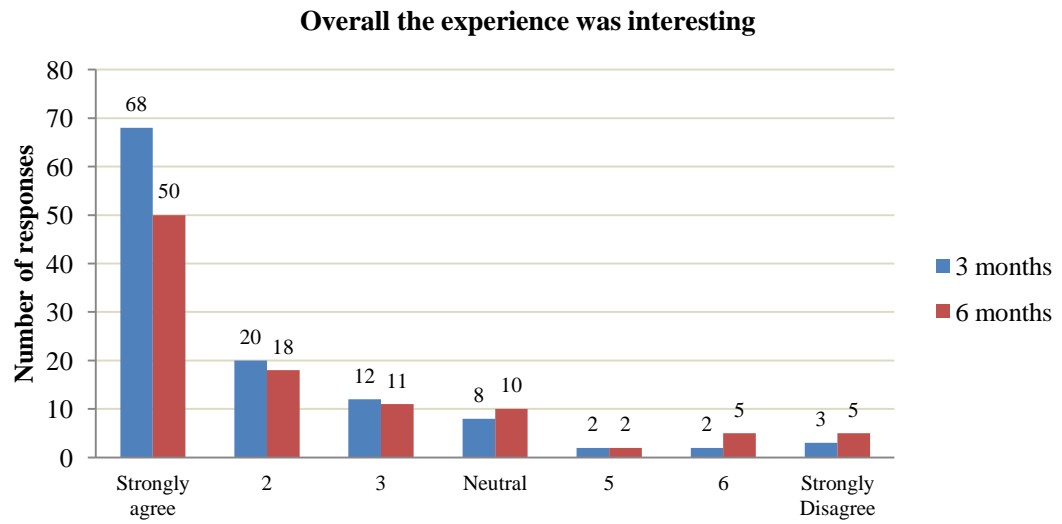


Figure 9.15 Continued

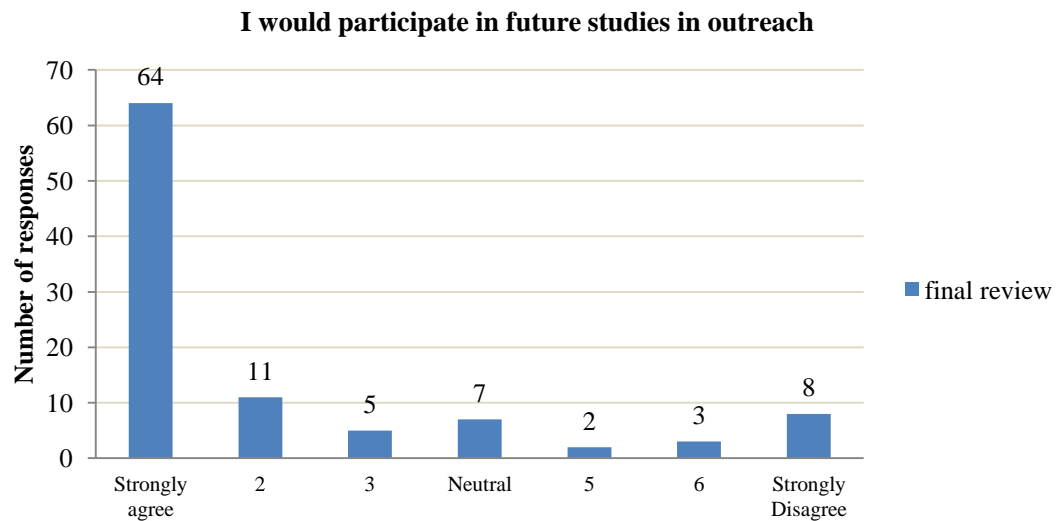
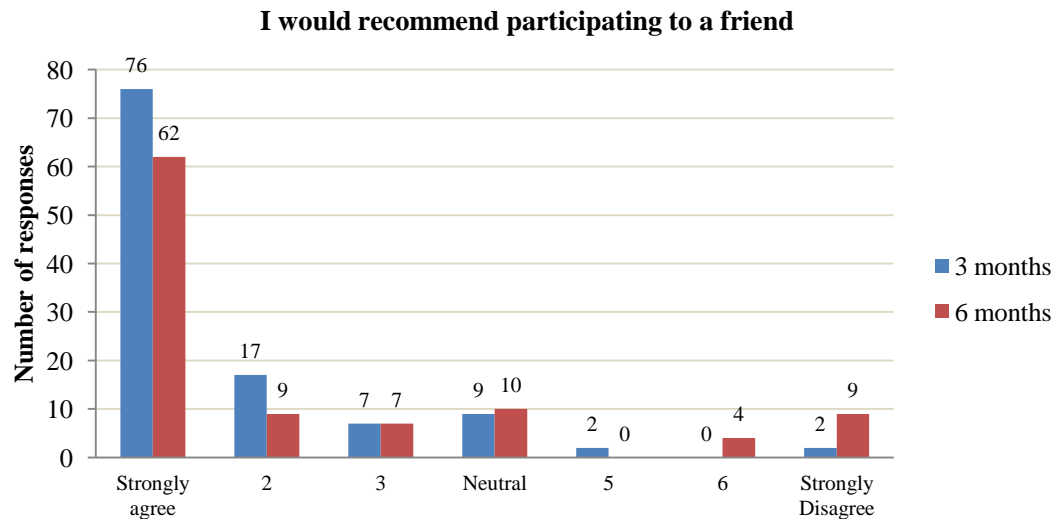


Figure 9.15 continued

9.4.5 Outreach Participant Post-Study Questionnaire Comments

The participant comments were positive and supportive of clinical research in dental outreach. The comments have been grouped by theme. The main themes covered were oral hygiene, experience during DOOHS and general praise for the outreach clinics. Some participants explained reasons for not continuing in the study.

Theme 1 - Oral Hygiene

The participants were very positive about the topic of oral hygiene and keen to improve their dental health.

“I have been cleaning my teeth the way the students want me to do since I first saw them.”

“It was good to get to know exactly how to clean my teeth & the best way to do it for my teeth. Advice given was excellent.”

“Only bleeding gums at present due to poor diet, taking action.”

“I am very appreciative of the care & attention shown by students & dr. My treatment has been successful. I do have problems with the advice given on flossing with brushes. I find dental tape effective. I am age 74.”

“I know I shouldn’t smoke as this is bad for my gums & teeth but it is v hard to stop & I have cut down to ten or so per day. I would like to keep what teeth I have left for as long as possible & I thank you all v much.”

“Keep up the good work. I’m trying!!!”

Theme 2 - Participant experience during DOOHS

The participants gave a positive picture of the research. They enjoyed the experience and the time taken with them. They acknowledged the hard work of the students and staff and appreciated this.

“Worthwhile experience - I should & will try to take more time in the cleaning process. Thanks to all.”

“I have found the students to be extremely competent, helpful & reassuring throughout my appointments.”

*“I thought the dental nurse ***** was great.”*

*“The treatment given by the students was extremely great & the attention to detail amazing. I would like to thank the students & Dr ***** & staff for the treatments received & the way they made me feel very welcome & reassured.”*

“The students were attentive. Would recommend to anyone to participate.”

“I found the study v helpful & useful towards maintaining good dental hygiene & health. I felt that the standard of student was v high & that they were all polite & professional in the way they carried out their duties.”

“Thanks for all the HARD work to both staff & students. I can smile again.!!”

“The students took time to explain everything, the experience was helpful & interesting.”

“Overall the experience was good but found out my teeth & gums not as good as I thought.”

“I felt most staff was good but others I found uninterested in my treatment/health.”

Theme 3 - General praise for the outreach clinics

The participants took the opportunity to generally praise the outreach clinics, staff and students for the treatment they received there.

“All the students I encountered on my treatment were confident, polite & extremely gentle in their approach. I can praise them enough.”

“Would like to comment on friendliness & helpful, attentive and kind staff/students.”

“They all do a fantastic job.”

*“The treatment given by the students was extremely great & the attention to detail amazing. I would like to thank the students & Dr ***** & staff for the treatments received & the way they made me feel very welcome & reassured.”*

*“This has been really good as it is v difficult to get an NHS dentist & I feel better in myself that my teeth are clean & well looked after every 6 months or so from now on.
Thanks.”*

“Glad all teeth sorted.”

“Have always had excellent service every time I have attended.”

“I can't thank them enough for what they do. Everyone was so good. Thank you.”

“Having had a morbid fear of visiting dentist have now conquered my fears & don't feel so uptight when I visit now, would recommend this place to anyone.”

Theme 4 - Reasons for not continuing in the study

Generally the reason participants withdrew from the study was due to lack of time. One participant offered to come back to take part in future research although they had found their own dentist!

“No longer attending student clinics as now have an NHS dentist but quite willing to attend at any time for further research etc.”

“Lack of time, problem with schedules.”

“Too far away from outreach centre.”

“Work commitments mean can't return until August therefore withdraw.”

“My only problem is I only knew about this appointment on Saturday when the post arrived. As a bus driver & with varying schedules, I need at least 2wks in advance so as my boss can jiggle things about to accommodate my appointment. All in all the students & staff are excellent whenever I have appointments.”

9.4.6 Post-study Outreach Participant Questionnaire Discussion

The participant post study data gives an insight into the outreach patient views of clinical research in dental outreach. However it should be considered that these are the views of the self-selecting cohort of patients who enrolled in the clinical research study. The views may not be representative of outreach patients in general.

Overall, those patients who participated in the study and returned for review enjoyed the experience, found it interesting, would participate in future research in outreach and would recommend participating to a friend. The participants considered the students to be enthusiastic, confident and explaining things well. They reported that they had the opportunity to ask questions and that the supervisor checked the student's work. The supervisors were viewed by the participants in general to be enthusiastic.

The views of the participants disputed staff and student pre-study concerns regarding outreach patients only wishing tangible dental work such as fillings done. It's possible that such patients would not have enrolled in the study. Outreach participants in DOOHS rated the receiving of preventive care first to prevention as being extremely important, followed by treatment for their gum, and closely by fillings, although gum treatment and fillings saw a flatter distribution curve. Participants felt that it was important that the students took their time with them and reported not to be concerned about coming to many appointments, which had been a concern of the stakeholders.

During the study there was only one phone call to the study phone from an outreach patient. This was a patient who had somehow received the study information late and wished to take part in the study. Unfortunately this patient could not be involved as the initial recruiting year group of students had finished their outreach attachments. There were no concerns or complaints from outreach participants during DOOHS. Dental outreach patients are supportive of clinical research in dental outreach.

Chapter 10: Discussion: Feasibility of Clinical Research in Dental Outreach

Summary

This thesis investigated the feasibility of clinical research in dental outreach. This was achieved through the implementation of a previously tested clinical research model, updated and adapted (DOOHS) to test the outreach environment's ability to support clinical research studies. Through the implementation of this study, barriers to and facilitators for clinical research studies in the outreach environment were identified.

DOOHS recruited 165 participants during the three month recruitment phase, from an original target of 1500. At three months 64% of these participants returned for clinical measures. This dropped to 55% at six months. Questionnaire returns saw 75% returns at three months and 63% at six months. All three groups (outreach participants, dental students and outreach staff) indicated that they would consider participating/collaborating in future clinical research studies. A cohort of dental students were dissatisfied with their research experience. Students and staff made recommendations regarding timing, design and delivery of any future clinical research studies in outreach.

It is considered feasible to deliver clinical research studies in the dental outreach environment. The dental outreach environment is considered suitable to support carefully managed, small scale clinical research studies.

10.1 Design and Protocol Development of Clinical Research Studies in Dental Outreach

This work identified that outreach staff and dental students wish to be consulted as early as possible in the design of clinical research studies for dental outreach. There was a general view from the staff and students that they wished to be involved at the

protocol stage as the outreach staff have an insight into their environment. Their collaboration with researchers at this early stage would be beneficial to future studies in the dental outreach environment. The DOOHS protocol was considered easy to administer but there was a recommendation that paperwork should have been refined to reduce the disruption to the clinics. The overall organisation of the outreach clinics impacted on the administration of the protocol. There was an overall feeling that DOOHS had been forced onto the clinics and the dental students, and earlier consultation with collaborating staff and students would have involved them and addressed this, assisting with 'buy-in' and attitude towards the clinical study.

Dental students' involvement with clinical research was seen as a positive curricular development by the Dental School Board. The implementation of DOOHS highlighted some of the problems of involvement with clinical research within the dental curriculum. The students wished deeper involvement with the study including assisting in the design and choice of study topic. The design and topic of clinical research study would need to be matched to the year of dental student so that it would be appropriate for their level of training at that point in the course.

10.2 Timing of Training and Clinical Study

The final year students were of the opinion that clinical research may be better placed earlier in the curriculum. A new curriculum which is currently being developed for Dundee Dental School could provide an opportunity for clinical research to be covered earlier in the course. Students training under the new curriculum will see dental patients sooner and begin acquiring dental skills from their first academic year. At the time of DOOHS, dental students did not begin patient contact until their third academic year and only attended outreach at the end of their fourth year and through final year. Therefore, under a new curriculum, there could be an opportunity to move a clinical research study into the third year, once the students have had experience of providing patient care. This would also be dependent on the timing of outreach attachments in the new curriculum.

The final year was chosen by default to implement DOOHS as the year who currently attend dental outreach clinics. There were some positive reasons to involve final year students. They have the skills to carry out clinical research and they are also experienced in consenting patients for dental treatment. During DOOHS the dental students utilised the skills acquired during their training and successfully discussed the study and recruited and consented participants. Students measured and recorded simple clinical measures and managed to complete dental treatment alongside delivering clinical research. The recommendation from the dental students, however, was that they would have preferred clinical research involvement earlier in the course and not in the busy final year. If this recommendation were implemented for future clinical research studies in dental outreach there may need to be consideration as to the level of students involved in the research and their experience in communicating with dental patients and the level of staff outreach support which would be required supervising less experienced students. The paperwork developed for DOOHS such as consent forms could easily be adapted and utilised for less experienced students as these prove to be simple to follow and, for example, would guide less experienced students through the consent process.

10.3 Choice of Clinical Study and Design for Outreach Clinics

The choice of oral hygiene as a topic was popular with dental outreach patients and considered appropriate by outreach staff and students. However the dental students reported that they did not find the topic very interesting. Future clinical studies in dental outreach should consider carefully not only what questions need to be answered but also which of these will be attractive to the dental students involved. Oral hygiene may have been a good choice for earlier years of students. By involving dental students in the choice of the study and the design process, students may be able to better understand why a particular topic has or hasn't been chosen and the reasons behind the research question choice and why the protocol is as it is.

The target number of participants required for DOOHS was too ambitious for the dental outreach clinics. Future studies in dental outreach should consider carefully any outcomes of power calculations and perhaps reconsider the research topic or

measurements to be taken if the numbers of participants required is too high. The sensitivity of the measurements taken in DOOHS could have been improved. However, a balance was required between this and the students' experience and teaching in the curriculum at the time. The limited number of exclusion criteria was good and allowed almost all patients who wished to take part in DOOHS to do so. Having such limited exclusion criteria would thus be recommended for future studies in outreach to allow the maximum number of outreach patients to be involved. This is especially important as, although there are large numbers of patients attending outreach appointments, many of these patients are repeat attenders and therefore the actual potential number of new participants is smaller than it may appear.

The return rate of participants in DOOHS was considered to be quite high (64% at three months returning for clinical measures and 55% at six months). Questionnaire returns were higher than clinical visits for measures (75% at three months and 63% at six months). The tracking of participants was variable between the clinics. Those clinics who organised their own forms, month by month and identified patients who were due review, were the most successful in achieving a return visit. Future studies in outreach should implement such tracking of participants or use an electronic reminder system for the clinics. The review visit timings of six months resulted in a second year group of students becoming involved in DOOHS. While this was positive, in that this second year group also gained some clinical research experience and were additionally completely blinded to the intervention the participants had received, this was outweighed by the negatives involved in fully training another year group who would only gain a small amount of experience and these students' feeling of disconnection from the research process having not been involved in the recruitment stage.

Although the questionnaires had been used by a previous study (Clarkson 2009) and had a high rate of return, the outreach participants reported that they were too long and wordy. Several of the questionnaires came back with written questions about the questions. Future studies in dental outreach should pilot questionnaires with a group of outreach patients for feedback before rolling it out on such a large scale. The research questions to be answered should also be tightened to reduce the number

of overall questions and choice of responses to simplify analysis. The physical collection of questionnaires from participants by the students was variable. Use of a dedicated research nurse could have improved this, and ideally the training of outreach reception staff to be involved would be recommended.

The method of allocation for participant ID numbers worked well for this outreach study. The same method could be considered for future studies in outreach especially if a randomisation phone line was not available to the clinics. One benefit of the system utilised was the ease of tracing the participant back to their outreach clinic and the treating student (identified from the separate numbers).

The identification of which patients were participants in DOOHS during their dental appointments was challenging. The use of the R4 system icon did not work well. It was too small and had been removed at one site. A clearer system is required. One suggestion which came out of this research was to use coloured appointment cards for participants as these could be used alongside the tracking of participants who needed review appointments.

10.4 Setting Up a Clinical Research Study in Dental Outreach

10.4.1 Approvals

Setting up a clinical study in dental outreach clinics relies on approval from many groups. Many of these approvals have to be secured sequentially, with the initial approvals obtained before the next organisation can be approached (Figure 5.4). This results in the process taking many months. One of the findings from both the outreach staff and dental students was that they would like to be involved at the start of the research design process in order that they could follow the research through and understand reasons behind the protocol. Unfortunately, this approach would be likely to make clinical research in outreach more difficult or even unfeasible, unless there was a clinical research element within the dental curriculum threaded throughout years. Such a clinical research element could include teaching students about research design and approval process during one academic year and then

delivering their clinical research study the following academic year. Such a method would require careful timetabling and planning.

The approval procedures required a vast amount of paperwork. Approval for the University to act as Sponsor required the least paperwork and was granted very quickly. The ethics approval followed, this process was guided by TAHSC and SDPBRN whose input is recommended for future studies in outreach. The protocol, questionnaires and ethics form were submitted and the author and PhD supervisor attended the ethics meeting, in order to discuss the research and answer, in person, any questions the committee had, such as the fundamental point that students carrying out DOOHS are collaborators and not participants. This saved time which would have otherwise been wasted with letters going to and fro and waiting until a following meeting for approval.

The approval which took the most time for DOOHS was the NHS R&D approvals as these had to be gained separately for each region involved. This delayed the start of the study. In order to approve DOOHS, each R&D department (a separate department for every NHS board) required:

- DOOHS Protocol
- IRAS Research Ethics Committee form
- CV from the Chief Investigator (Senior Dental Officer for Outreach)
- Ethics approval letter
- IRAS Site Specific Information form
- NRS-CC Certificate of compliance
- Site Specific Assessment Review (carried out by each R&D office)
- Research CVs from all the collaborators (i.e. outreach staff and all dental students)
- A nominated Principal Investigator for each outreach clinic

OHSAS clearance also had to be obtained for the author for each different region. This is required if the lead researcher is to physically see patients in that region and take clinical measures as part of the study. The OHSAS clearance involves

examination at the individual clinics. The researcher has to wait for the appointment from OHSAS. This took up to a month for some regions and the travel time to clinics such as Inverness could take up a day's work for a half hour appointment.

The OHSAS clearance for the dental student researchers was already in place through the University of Dundee Dental School, as they provide patient care on the outreach clinics. As they do not hold honorary contracts they do not require further clearance from each health board. Having OHSAS clearance across a range of regions would be one benefit of running clinical research in dental outreach. It would give the ability to sample the population across a range of different regions.

Following the process of setting up DOOHS, a number of conclusions can be made with regards to setting up clinical studies in dental outreach:

- Involvement of knowledgeable research groups such as TAHSC and SDPBRN in the protocol development stages is essential
- Dental School approval is required for dental students to take part in clinical research
- University Sponsor approval can be straightforward for low risk studies
- There is a benefit in personally attending the ethics board meeting
- Students are considered collaborators when carrying out research procedures
- Students can consent participants but require the process to be completed by a registered dental professional, who can be a research trained registered dental nurse
- NHS R&D approvals can take a considerable amount of time
- Clinical studies in dental outreach clinics should aim to have approvals in place the term preceding the start date of a study
- Dental students do not require additional OHSAS clearance in place for the outreach clinics they attend but any additional researchers will need separate clearances for each NHS area

Overall, it is possible to gain necessary approvals for low risk clinical studies in dental outreach clinics but a minimum of three months should be allowed to enable

all approval procedures to be completed. This does not include time to complete paperwork.

10.4.2 Organisation of Outreach Clinics

As there was little consistency in the organisation and layout of the outreach clinics, the student researchers reported difficulties in locating research materials during DOOHS. This proved to be a barrier to the delivery of the clinical research. The clinics which had organised a 'research area' such as Kirkcaldy, where a desk with all the materials was laid out clearly for the students, performed better at recruitment and reviewing participants. There were also fewer mistakes on the CRFs from these clinics. It is difficult to say whether this was purely due to the better organisation of the research materials or the overall attitude of the staff towards the clinical research. The students did however indicate that the more organised clinics were easier to carry out research in. Future studies in outreach should have a designated area which is easy to see on entering the clinic and clearly labelled to assist students and staff. Some visits of staff between clinics could be beneficial to allow outreach supervisors and nurses to discuss and swap ideas on the organisation of clinical research at the outreach clinics.

10.4.3 Nominated Research Staff

Clinical research studies in dental outreach clinics need transparency in relation to responsibility for each research duty. The allocation of the duty to complete certain logs was left open to the clinics to decide during DOOHS. This resulted in much variation between the clinics in how, when and if log-sheets were completed. Each outreach clinic had a PI, however, it became clear during the delivery of DOOHS that they were not always on site or may have been busy treating their own patients at times when DOOHS was running. As such, different staff were often responsible for the day to day running of the outreach clinics (and therefore overseeing DOOHS). When training was offered at the start of the study it was not clear to the author exactly how many different supervisors there were at each outreach location and how many different nurses rotated through the clinic. Equally, it was perhaps

not clear to the outreach clinics how essential the training would be to the smooth running of the study. That said, tackling this by training of all members of staff should be approached with caution. At Inverness, initially only the two staff who supervised the clinic were trained. They then requested the training be rolled out to all the dental nurses who rotated through the clinic. As a result this outreach clinic had the highest number of staff trained in GCP and the protocol. This was also the poorest performing clinic. It seemed that the training of too many staff resulted in everyone assuming that someone else was taking responsibility for the study.

To give clarity, the recommendation would be that the supervisor who has overall responsible at each outreach clinic retains the responsibility for the paperwork, although it would be accepted that they could supervise and then delegate this task to additional staff and nurses as required.

10.4.4 Student Responsibilities

Student responsibilities during DOOHS were to:

- distribute Patient Information Packs to outreach patients
- discuss the study with potential participants
- check eligibility
- carry out consent procedures, in collaboration with trained outreach staff
- allocate study identification code to participants
- collect the participant questionnaire
- record plaque and bleeding
- deliver oral hygiene instruction according to group allocation
- make participant review appointments
- complete log sheets
- carry out dental treatment for the participant if required
- place research data in the collection box

The dental students managed the majority of these research tasks. In particular, there was comment during DOOHS that they were particularly strong at discussing the study, checking eligibility, carrying out consenting participants, and delivering the oral hygiene instruction. The measures were recorded by the students and the supervisor feedback was that this was completed to a good standard. There were a small number of CRFs with mistakes in the addition and calculation of the O'Leary plaque and bleedings scores. These mistakes were easily identified and rectified by the author during site visits. It would be recommended that any future studies in outreach use an electronic method of calculating any such information to reduce the chance of mistakes. The relatively small number of CRFs completed during DOOHS made checking and correction straightforward, however any larger scale study would find this task very time consuming. The allocation of the participant ID by dental students worked well.

The majority of students managed to complete simple items of patient care alongside research but it was reported that there was not enough time during outreach appointments to carry out both clinical research and advanced restorative procedures such as endodontics.

The dental students were initially slow at distributing the patient information for DOOHS. This was considered to be partly due to them forgetting, due to the busy nature of the outreach clinics, but mostly due to their initial attitude toward the research. It would have been more predictable (albeit more expensive) to have the patient information posted to the outreach patients ahead of their appointments. Alternatively, it would be an option to train outreach reception staff and negotiate this as an additional task during the research period. Future studies in dental outreach may wish to explore these options. The dental nurses were very good at handing out the packs and introducing the study to patients and would make a good alternative if the reception/administrative staff were not able to assist.

The collection of completed participant questionnaires by dental students was a surprising challenge during DOOHS. The author witnessed participants returning with questionnaires only to have this completely ignored by the treating dental

students and requiring intervention in order that this was collected. The allocation of this task to a research nurse on the clinic would be recommended. Alternatively, if the study were funded, students may be motivated by a small payment for collection of returned research materials.

There were some areas where dental students struggled with research such as the completion of the log sheets during the study. The lack of consistency between the clinics made this more of a challenge. Dental students have many tasks to complete towards the end of a patient appointment (writing notes, completing reflective logbooks, and during this research, completing the CRF calculations). To then have to locate and complete log sheets additionally is too much responsibility when they have another patient due in and more notes to read in relation to this. Ideally, future studies in outreach should have an electronic method of centrally logging participant information so that dental students on the clinics do not have to use their clinical time completing paper log sheets, many of which involve some degree of duplication. If it is not possible to digitise this process then a designated research nurse, at each clinic, with this responsibility and overseen by the PI, would be recommended to ensure consistency of completion. During DOOHS, many of the outreach clinics abandoned some of the log sheets and produced their own alternative which was simpler than those provided by TAHSC and much more effective in dental outreach. Future studies in outreach should consult outreach staff and complete a pilot of any suggested paper logs in real time to assess what is manageable on the clinics.

The booking of review visits was another unforeseen challenge. It was anticipated that the appointing of an outreach participant to return at 3 months would be straightforward. In reality, a variety of things happened to participants: some were appointed and returned and had their review as organised, some were appointed but when they attended at 3 months they needed other treatment and thus the research review was forgotten. Others made an appointment sooner for routine care and as these appointments continued, the review appointment was forgotten. Three of the outreach clinics, as mentioned, had organised their own log sheet detailing the month when each review was required. These clinics sent out specific research

appointments as required and the nurses, or in one case supervisor, at the clinics highlighted to the student when the patient attended that it was for DOOHS review and handed the student the CRF. This worked well for these clinics and would be recommended as a procedure for future studies in dental outreach.

The research tasks which are reasonable for dental students to complete on outreach clinics during their usual patient appointment times are:

- Discuss research projects with potential participants
- Check participant eligibility
- Carry out consent procedures, in collaboration with trained outreach staff
- Allocate study identification codes to participants
- Record measures
- Deliver a simple intervention or treatment

In conclusion, dental students can carry out clinical research procedures in dental outreach, but may require assistance with administrative tasks.

10.5 Dental Undergraduates as Clinical Researchers

While it has been established that dental students can carry out clinical research in dental outreach, should they actually do so?

The British Educational Research Association (BERA. 2011) has published guidelines regarding the conduction of research involving dental students where the students are the studied population. However, dental undergraduates actually conducting clinical research studies, in situations such as during DOOHS, seem to fall out with the remit of such guidelines. Such students are not the subject of research; they are collaborating with the research study in the role of clinical researcher. The undergraduates involved in DOOHS had completed all the necessary training they needed to in order to legally be allowed to carry out clinical research. The participants involved in DOOHS viewed the students to be confident

and competent during the research study and were satisfied that the students explained everything well. The supervisors were satisfied with the undergraduates' research measures and delivery of the intervention. Undergraduates have the ability to carry out clinical research. Whether they should or not may depend on the educational benefit of their involvement in clinical research.

The Dundee University dental curriculum, at the time of DOOHS, had little research teaching for dental students. Although teaching staff discuss evidence based dentistry with the students and reference literature in their lecture material, this did not appear to establish the premise for students that research has a place within general dentistry, that the evidence has to be produced from somewhere and that research is something they could carry out. A small number of students (two or three a year) at that time would carry out their own research as part of an intercalated BSc between 2nd and 3rd year, but this research was generally lab based. The DOOHS research students were the first group of dental undergraduates to go through Good Clinical Practice training and collaborate in clinical research.

DOOHS was initially met with a great deal of resistance from the student year. The mind-set of the dental students was that they were training to be dentists and not researchers. They didn't see clinical research as part of general dentistry and resented it being introduced into their final year. The introduction of research into the final year may have come as a bit of a surprise to the students since students had never before carried out clinical research in dental outreach, and haven't since. Unfortunately, the opportunity was sold poorly to the year and the training they received was not fit for purpose and turned them off clinical research. Added into the mix were the numerous delays involved in gathering the necessary permissions for DOOHS and a start date for the study three months after their training. This resulted in the study having a poor start. Many lessons were learnt through the delivery of clinical research with this pilot final year of dental students. One finding being the negative attitude of the dental students towards clinical research and this should be considered.

DOOHS encountered significant resistance from final year dental students at the time. The negative attitude of some of the students towards clinical research quickly spread to the rest of their year group. The students complained to staff about having clinical research as part of the curriculum. The students did not see research as relevant to them or as part of general dentistry. The topic of this research study was not something which the final year dental students were interested in. Oral hygiene instruction is fairly simple and the students saw it as mundane at that stage of their training.

The involvement in a clinical research study in outreach could have been sold much better to the year group. It was difficult for the students - being the pilot group, there were many unknowns as to how the research would work out. The benefits of collaborating to them were ethereal. In retrospect, it may have been beneficial to have had some general practitioners who carried out clinical research in their primary care practices come and speak to the year group. This would have enabled the students to see that clinical research is something 'normal' in general practice dentistry and not an unreasonable subject for them to be involved with. A symposium with a general introduction and some breakout sessions covering research design and processes would be recommended as a general introduction for the students before collaborating in future studies in dental outreach. The Dundee University Dental School curriculum at that time followed the GDC 'The First Five Years' (GDC, 2008). This listed one of the learning outcomes to be possession of research skills. This had not however been implemented before by actually having dental students carrying out clinical research. It therefore was not considered by the students as something they should be doing as part of their dental training.

There were however a minority of students who indicated through the student questionnaire, that clinical research was important to them. Indeed, several of the students involved in DOOHS included the experience in their curriculum vitae when applying for postgraduate training posts and this involvement in clinical research afforded these students additional points towards securing an interview for these training posts. The view from the student body was that the curriculum needed to change if they were to be involved in clinical research. The students felt that the

topic of research addressed through DOOHS would be better tackled earlier on in the curriculum. Currently a new curriculum is being written. This could provide an ideal opportunity for Dundee Dental School to embed clinical research teaching throughout the five year course and perhaps also include studies in the undergraduate curriculum. Early introduction of the concept of clinical research and the generation of evidence in primary care could help towards changing the mind-set of the undergraduates regarding clinical research. This could provide an opportunity for students to understand that primary care dentistry not only benefits from evidence but can actually contribute towards its generation. Dundee Dental School is currently affording students the opportunity to get involved in research through internships. These are optional. It may possible to expand this to clinical research and afford students such opportunities within the dental outreach clinics, although this would only be suitable for short (perhaps 1 visit) projects.

Recommendations from this research with regard to the Dental Curriculum:

- Research teaching should be incorporated early within the curriculum so that it is considered as normal and research content expanded up through the years
- Collaboration in clinical research should not be optional for students initially
- Promote the benefits of clinical research better to staff and students

10.6 Training Requirements for Clinical Research Studies in Dental Outreach

Clinical research studies in dental outreach require both the outreach staff and dental students to be trained in the research protocol and Good Clinical Practice (GCP). DOOHS was the first study to require GCP training for dental students. Therefore the help of TAHSC was enlisted who had experience in training clinical researchers. Unfortunately TAHSC had no experience with dental undergraduates and their approach was not taken well by the students. The ‘blanket’ form of GCP training delivered by TAHSC contained too much research information, much of which was irrelevant for the dental students. It was interesting to observe that TAHSC were clearly accustomed to speaking to research students who had an interest in gaining

whatever information they could from TAHSC presentations rather than trying to enthuse a group of undergraduate students to promote clinical research. The training was also delivered early and appeared out of context. There were reasons behind the timing of delivery. The students were not in Dundee very often as their outreach attachments take them all over the East of Scotland. Therefore the training had to be slotted in. The protocol training was also not well received and the relevance was difficult to teach out with the context of the clinic. What the students preferred was the training video which showed the clinical setting and a run through of procedures. The students could relate to this better and indicated that they used and referred to this as a reference guide as and when required during DOOHS.

The second year group of students and the outreach clinics benefitted from the feedback of the initial students' endurance and were spared the epic, three-hour-long training session. Before delivering training to the outreach staff, the author consulted with TAHSC and shorter joint training sessions were undertaken. These contained much less information and only that relevant and required for the delivery of DOOHS. These sessions were refined so that the author delivered them fully including GCP information. This information was then woven with the protocol to put it into context and the relevance of the specific components was clearer. The outreach staff feedback from the session was favourable. When the following year group of students were trained, they received the same revised training as the staff and the reception from the students was more positive.

Training for future dental students carrying out clinical research in dental outreach should be delivered as close to the start of a clinical study as possible and should cover the main points of GCP while making these relevant to the particular study. Training delivered by clinical dentists is better received by dental students. One morning session of training perhaps delivered as part of a research day would be the author's suggestion for future studies.

Outreach staff also required GCP training and DOOHS protocol training. The training for staff was complicated by:

- Distance between the outreach clinics
- Turnover of staff working in the clinics
- Availability of staff
- Time

TAHSC representatives attended the first outreach staff training session in order to deliver the GCP components. After this session the author delivered the combined GCP and protocol training to the other outreach clinics. In order to deliver the training the author travelled to each outreach clinic. This took up a whole day for Inverness and Aberdeen outreach clinic and one session for the other clinics due to the closer proximity to the Dental School.

One problem which was not immediately apparent was the number of staff working in the outreach clinics and the turnover of staff in some of the areas. In Inverness, initially two supervisors were trained. The clinic then requested further training for the large number of outreach nurses which rotated through the clinic. This took up two days including the travel time. As the nurses rotated between the CDS and the outreach clinic, for some of the nurses it was some time before they were involved in the study and therefore the information was possibly not retained. In Fife, Kirkcaldy had three staff trained. This small team then rolled information out to the reception staff and others working in the clinic. This system worked very well and the paperwork and management of reviews was completed to a high standard. The same was true of Springfield, Arbroath and Kings Cross, Dundee.

The time available for training varied between regions. In Tayside and Highland, the clinical dental directors allowed a session for staff training. In Fife the clinical dental director allowed an extended lunchtime for the staff, which was also the case in Grampian.

Staff in the clinics reported back that the training video was the most useful aspect of their training. The video allowed staff to review the protocols close to the start of the recruitment stage of the study which helped the problem of the training being

delivered some time before the start of the recruitment. This also enabled the training to be cascaded to other outreach staff as and when required.

Future staff training for clinical studies in dental outreach should train a core number of outreach staff (two supervisors and two nurses if possible) and from this core have a nominated person who will be responsible overall at the clinic for the coordination of research. Training videos with real-time run through of paperwork and procedures are also to be recommended. These should be available for staff to refer to during the research period. If possible a dedicated research nurse should be nominated or appointed for the research period. The rotation of nursing staff between CDS and the outreach clinic during a clinical research study should be discouraged as this adds to confusion in the clinic. Shorter duration clinical research studies would be easier for staff to manage and may be delivered over one academic year. Training should be delivered as close to the start of any clinical study as possible or a recap session offered to the clinics at the start of a study. GCP training should be delivered alongside the protocol so that the relevance is clear.

The main findings with regard to delivering training for clinical research studies in dental outreach were as follows:

- Deliver training as close to the start of a study as possible
- Make it relevant and concise
- To be delivered by enthusiastic dentists or dental researchers
- Deliver training as part of an overall research day so it is within the curriculum, but keep individual groups small
- Carry out GCP and protocol training together
- A ‘workshop’ style is suggested rather than lectures
- Train a core number of people at each clinic and ensure everyone knows who is taking overall responsibility
- Have a designated research nurse (this could be the head nurse)
- Use training videos
- Offer a revision or catch up session at the beginning of the study
- Consider training dental students alongside the outreach staff if possible

- Organise CPD for outreach staff for time spent training.

10.7 Delivery of a Clinical Research Study in Dental Outreach

10.7.1 Pack Distribution

Clinical research studies require patients to have Patient Information Packs at least 24 hours prior to recruitment into a study. DOOHS protocol suggested dental students hand out patient information, and then recruit the patient at their next appointment. This method was not effective for dental outreach. Dental students were reluctant to hand out packs, or forgot. As the student handing out the information was not likely to be the student who ultimately recruited the patient (due to the movement of students through the clinics) there was no motivation for students to distribute packs. The outreach clinics which distributed the highest number of packs were those where there was an outreach supervisor (Kirkcaldy) or head nurse (Springfield and Kings Cross) either handing out pack themselves or encouraging the students by physically putting the envelope in the dental student's hand while the patient was in the chair. Around 28% of patients given a pack consented and participated in DOOHS. This figure was considerably lower than the 57% which consented and participated in Clarkson's study, however those participants recruited by Clarkson's researchers had the additional incentive of receiving a power toothbrush. The main findings with regard to pack distribution during DOOHS were:

- Outreach clinics will distribute patient information for a clinical research study
- Dental nurses are most proactive in facilitating this
- Around 28% of outreach patients invited, participated in DOOHS
- Students are not motivated to hand out packs if they will not be recruiting the patient at the next appointment.

It is recommended for future studies in outreach that information packs are posted to patients so that they receive them in advance of their outreach appointment, or that either dental nurses or outreach reception staff distribute packs out to the patients.

10.7.2 Participant Recruitment

During DOOHS, participant recruitment was challenging. Outreach patients were generally happy to participate in the clinical study however there were barriers to them doing so. These were:

- Not having received the participant information pack
- Being asked to participate by their treating dental student, which was influenced by additional factors:
 - The student remembering to ask the patient if they wished to participate
 - The student having time to recruit the patient during the appointment
 - The individual student's motivation to recruit a participant
 - The student's attitude towards the clinical research study

The participant receiving the pack in advance has already been discussed in 10.7.1.

The dental student's ability to remember to recruit the participant could be increased by dental outreach staff reminding them when they go through the notes at the beginning of the session. The placement of a 'research area' in the student's field of view while on clinic, was thought to have improved this in Kirkcaldy. However this was also at least partially to do with this clinic's positive attitude towards clinical research in outreach. Better branding of future clinical research studies in outreach could help with this and the direct suggestion to clinics that a 'research area' be organised should be part of the research training. It should be kept in mind that in some of the smaller outreach clinics this would be difficult as there is limited space available.

Students on the whole, have time to recruit participants to a simple clinical study during their usual outreach appointments for routine treatment. The amount of time they have available varies from clinic to clinic as some appointments are for one hour (Aberdeen) and some are for 1hr 30mins (Tayside and Fife). The flexibility of the appointment time varies between clinics. The amount of time it took a student to recruit a patient during DOOHS depended directly on the set up of the clinic and the amount of support available. Some of the outreach clinics left students to 'get on with it' and at these clinics the study materials were also difficult to find. This resulted in students not only taking much longer to complete research, as they had to spend time looking for materials, but additionally that they quickly lost the motivation to do so. This was reflected in Inverness where the materials were difficult to locate and this clinic ultimately had the lowest recruitment rate.

The dental student's attitude towards clinical research was only touched on during this work. This area could easily be a subject for future research. Each student's attitude was influenced by their peers and by outreach supervisors and their opinion as to the role of a primary care dentist and the placement of research in the dental curriculum. The clinics where supervisors were of the opinion that research was important were able to motivate the students into recruiting patients. At outreach clinics where supervisors had not taken responsibility for the research themselves, or where their views on clinical research were negative, the students were poorly motivated to recruit patients. A change in the dental curriculum would be required to alter the opinions of dental students towards clinical research. The findings from the student post study questionnaire indicated that students felt motivated to do what the dental curriculum and supervisors wished them to do. At that time, the curriculum placed much emphasis on achieving measurable clinical experience such as the number of restorations completed to a specific standard, or the number of advanced treatments completed. If this attitude is to be challenged the dental curriculum will need to place equal, or at least greater importance on clinical research. Dental students can successfully recruit participants but need an incentive to do so. Additional recommendations from this study regarding recruitment to clinical studies in dental outreach were as follows:

- Have one member of staff per site taking responsibility
- Have designated areas where research materials can be clearly found. The layout of these areas (e.g. a table) should be consistent between outreach clinics
- Have an incentive for dental students to carry out the clinical research
- Do not attempt large scale studies. Recruitment of small numbers of participants is achievable in dental outreach clinics
- Post out patient information or involve reception staff/key nurses in distribution of information to patients.

10.7.3 Participant Returns

DOOHS protocol had suggested that the participants' recall appointments should be booked by the dental student while making further appointments for routine dental treatment. In practice, this didn't work for the outreach clinics. The students had too much to do at the end of the research visit with collating paperwork, calculating the charts and writing up the patient notes. Adding in the complication of organising a further research appointment was too much. In reality the clinics each had their own method of reappointing the participants. The clinics which were most successful at getting participants to return for review ran their own log sheets with the patient name and month the review was due on. They recalled these patients separately to any additional dental appointments which had been made. The NHS Fife clinics additionally had a text reminder which went out to patients the day before their dental visit to remind them to attend. This may have increased the number of participants returning for review. Since DOOHS, this method of appointment reminders has been implemented in NHS Tayside clinics. The numbers of participant's returning to DOOHS were favourable in comparison with other primary care studies on oral hygiene instruction. DOOHS saw 64% participants return for clinical measures and 75% questionnaires at three months and 55% return for clinical measures, 63% questionnaire returns at six months. Clarkson's group reported 31% of participants were required to return for follow up measures in their patient RCT and 39% participants in the cluster RCT, these numbers were substantially lower than those returning during DOOHS. Woelber's group (Woelber et al. 2015), who recently conducted an oral hygiene behaviour change

study, saw 81% of participants return for questionnaire measures in their practice based research. This study had recruited a total of 126 participants from 4 practices and the review was carried out after 6 months. This return rate is substantially higher than that achieved during DOOHS. Their participants received oral hygiene kits which may have provided an incentive for participation and return visits. It is also likely that general dental practice patients are used to returning every 6 months for dental examination whereas outreach patients have often not attended a dentist for many years prior to their outreach treatment and do not have the same relationship with the clinics, thus being out of the habit of returning for review. This may have affected return rates during DOOHS.

Key findings for reviewing participants in dental outreach studies are:

- Pilot log sheets within the clinics
- Have a small number of staff organising review visits (ideally one and a back-up)
- Have separate review appointments
- Organise reviews month by month/fortnight by fortnight depending on the study
- Consider appointments out-with the student term times if required if the OHSAS is in place for the lead researcher
- Mail out questionnaires to participants
- Another cohort of students can successfully carry out review visits to complete the research however students dislike being brought into a study at the review stage - therefore shorter clinical studies are to be recommended.

10.7.4 Paperwork for Clinical Studies in Dental Outreach

Dental students and outreach staff struggled with completion of all the necessary log sheets for clinical research studies within the standard outreach appointments. Dental staff sacrificed their lunch times to complete paperwork at some sites. The paperwork could be monitored easily by the research manager due to the low recruitment rate but if DOOHS had recruited the target number of participants this would have been difficult. Future studies in dental outreach should utilise

technology in order to populate the vast number of logs which are required by GCP for clinical trials.

Outreach clinics need a high level of support with paperwork at least in the initial stages of clinical research. Key findings:

- Use digital methods of logging participants and tracking them
- Offer outreach clinics a higher level of administrative support in the initial stages of clinical studies

10.8 Disadvantages of Clinical Research in Dental Outreach

The disadvantages of carrying out clinical research in dental outreach can be split into the following areas:

- disadvantages to dental students (10.8.1)
- disadvantages to outreach staff (10.8.2)
- disadvantages to outreach patients (10.8.3)
- disadvantages of dental outreach as a research environment (10.8.4)

These findings will now be discussed.

10.8.1 Disadvantages of Clinical Research in Dental Outreach to Dental Students

During DOOHS, dental students collaborated in a clinical research study. This was the first of its kind and the students involved (two year groups) all gained experience of clinical research in primary dental care. Overall, there was little disadvantage to dental students. When asked whether they found carrying out clinical research stressful, embarrassing or difficult the overall view from the year group was neutral to these questions. Students did not however feel that it was something they should be doing as dental students.

Dental students were of the opinion that the patient appointments were disrupted during the clinical study and that they found it difficult to carry out patient treatment alongside clinical research. This disruption was considered to be the main disadvantage to dental students.

The student groups involved in the study reported finding clinical research confusing and were of the majority opinion that it would not improve their future career prospects, nor was it considered to be of benefit to them in general. These disadvantages could be addressed by a better introduction to clinical research within the curriculum.

The use of dental outreach clinics as a platform for clinical research for dental undergraduates was considered to be disadvantageous due to the fact that dental students only attend outreach for a short time during their five years at dental school. The result of this was that students only got to experience a small part of the whole research process and could not see research projects through to completion. The students' experience with clinical research is therefore limited in this environment. While this was considered to be a disadvantage, it should be remembered that they would have had no experience in clinical research studies as part of their undergraduate training without this study. Overall, the students did consider that clinical research should be part of the dental undergraduate curriculum.

10.8.2 Disadvantages of Clinical Research in Dental Outreach to Outreach Staff

The disadvantages to outreach staff were difficult to assess due to the split in many of the questionnaire responses, and low rate of questionnaire return. The split in the responses should be kept in mind and the perceived disadvantages were the views of a minority of staff and not the general viewpoint of all staff. The disadvantages to outreach staff were considered to be: the increase in stress while supervising the clinics, and the disruption to the outreach patient appointments. The outreach clinics were considered to be more challenging to supervise during the clinical study and the students needed more support during this time. These disadvantages could have been overcome by offering the clinics further staff support during the patient

recruitment phase. In particular with the paperwork. Some of this could be improved if the paperwork could be digitised in some way. The amount of support students needed could be improved at some of the clinics by providing a designated research area with all the materials in one place.

The author noted further disadvantages to staff in terms of time. In three of the outreach clinics (Kirkcaldy, Springfield and Kings Cross) staff were using their lunchtimes to catch up with research paperwork. This no doubt added to staff stress during the research period. If disadvantages of clinical research to outreach staff are to be minimised in future studies in outreach, research paperwork must be reduced and electronic systems of management be implemented.

10.8.3 Disadvantages of Clinical Research in Dental Outreach to Outreach Patients

There were very few reported disadvantages to the outreach patients. Outreach patients were happy to take part in the research and the questionnaire feedback was very positive. The perceived disadvantages are reported from the dental students and outreach staff, namely the disruption to patient appointments and the clinics being more hectic during the research period. A small minority of participants reported that they had attended for review and had had other dental treatment carried out instead of research measurements but as they were still receiving dental care, this was not considered to be a particular disadvantage. A number of participants needed to attend for appointments out with the students term time. These participants were attending only for research review, so this extra appointment could be considered as a disadvantage. This was only reported to be a problem by one participant from NHS Highland who had to travel some distance to the outreach clinic, that particular participant therefore did not attend for clinical review. Future studies in outreach could minimise this disadvantage by making it clearer to participants at the start of the study that they may be asked to attend for review out with their usual outreach dental care appointments.

10.8.4 Disadvantages of Dental Outreach as a Research Environment

This study aimed to investigate dental outreach as an environment to support clinical research. There were identified disadvantages of utilising dental outreach clinics for clinical research studies:

- It is a teaching environment:
 - Dental students are collaborators in the research and require support to carry out research procedures
 - The dental curriculum does not currently require dental undergraduates to collaborate in clinical research, this reduces the acceptability to dental students
 - Dental students have a varying interest in research and require incentive and motivation
 - The function of outreach clinics is to provide dental care: clinical research is not considered routine in this environment
 - The times at which research can be carried out by undergraduates are dictated by the academic year, this makes review appointments challenging
 - Outreach staff need to supervise other, sometimes complex, dental procedures alongside research
 - Patients attend for repeat appointments which results in the patient pool for recruitment being fairly stagnant

- The clinics are in different NHS boards:
 - NHS R&D must be sought for each area independently
 - OHSAS clearance must be in place for each area for researchers (dental students are exempt from this)
 - The layout of each clinic is different and it is difficult to standardise for the students
 - There is difficulty getting outreach staff together for training: there is one outreach training day each year where this could be possible but its primary purpose is to cover other teaching topics

- There is a lot of travel involved for research management, this reduces the time available to support the clinics. Clinics closer to Dundee University are easier to support but those further away, for example Inverness, are challenging
- The organisation of staff in the different boards is inconstant, some clinics are static with regards to nurse support whereas in NHS Highland dental nurses rotate regularly, and this makes it is difficult to have one person take sole responsibility for clinical research at this clinic.

10.9 Advantages of Clinical Research in Dental Outreach

The advantages of carrying out clinical research in dental outreach can be discussed under the following areas:

- advantages to dental students (10.9.1)
- advantages to outreach staff (10.9.2)
- advantages to outreach patients (10.9.3)
- advantages of dental outreach as a research environment (10.9.4)

10.9.1 Advantages of Clinical Research in Dental Outreach to Dental Students

The dental students involved in DOOHS all gained first-hand experience of clinical research. They also gained additional experience in the particular study topic (oral hygiene instruction and in recording the periodontal health of the dental outreach patients). They gained new skills including experience in consenting participants for a clinical study and the paperwork involved in clinical research studies.

Overall, the students gained an insight into dental research in primary care. After carrying out clinical research in dental outreach attachments the students were of the view that this had demonstrated to them research could be carried out in general practice.

A number of the students involved in DOOHS included their experience in their CVs when applying for hospital training positions. Their involvement with clinical research awarded their application an extra point towards gaining an interview.

For the students who did not enjoy their experience with clinical research, they still gained additional experience and an insight into how challenging it can be to gather the evidence which feeds into guidelines.

10.9.2 Advantages of Clinical research in Dental Outreach to Outreach Staff

During DOOHS, dental outreach staff were able to get involved in clinical research within their usual working environment. They reported to have gained skills and this was achieved within their usual working hours. The dental outreach staff involved with DOOHS were of the opinion that their involvement had been enjoyable overall (7 agreed, 2 disagreed). They were of the opinion that their involvement had improved their understanding of clinical research and that they learnt new skills. Eight of the outreach staff returning questionnaires indicated they planned to take part in clinical research in the future.

After DOOHS the head outreach nurse from one site went on to secure a research role with SDPBRN and involvement in further primary care clinical trials. One of the outreach supervisors went on to study for a masters, while a further supervisor undertook specialist training and a PhD.

10.9.3 Advantages of Clinical Research in Dental Outreach to Outreach Patients

The outreach patients involved in the study were all very complimentary about their involvement with clinical research and indicated that they would recommend the experience to a friend. Several of the patients commented in their questionnaires that they appreciated the oral hygiene instruction. The focus on prevention could only be of benefit to them. The patients gained additional information about oral

health care and the intervention group had a sustained and measurable health benefit at 3 months.

Overall, clinical research in dental outreach gives the participants a little more time in the dental chair with the students (which they enjoy). It would be expected that, if rolled out further, the study would start to gather information as to which treatments are effective in the dental outreach clinics.

10.9.4 Advantages of Dental Outreach as a Research Environment

Dental outreach was found to have several advantages as a clinical research environment:

- Although it takes some time, approvals can be gained in order to carry out clinical research in dental outreach.
- Dental outreach patients are interested and happy to be recruited to a clinical research study
- Dental outreach participants return for review and complete questionnaires
- Dental outreach appointments are (generally) of a length which are supportive of carrying out clinical research alongside simple dental treatment
- Dental students are able to carry out research procedures as collaborates in the research and are competent in consenting participants, completing simple measures and delivering an intervention
- Dental outreach staff are generally interested in clinical research
- Clinical dental directors are supportive of clinical research being carried out in their outreach clinics. They additionally allow small amounts of time for training and additional clinics to be held in order to review participants (NHS Tayside and Fife supplied a dental nurse for reviews to be carried out out-with student term time)
- Outreach clinics already have the necessary equipment for plaque and bleeding measures to be carried out
- Dental outreach nurses are very supportive of clinical research and keen to be involved

- Dental outreach nurses know the patients and are able to keep track of recalls
- Dental outreach nurses and outreach staff are able to encourage less enthusiastic students during clinical research studies.

10.10 Identified Barriers Towards Clinical Research in Dental Outreach

This work aimed to identify barriers to clinical research in dental outreach clinics. These barriers have been discussed throughout the thesis. This section aims to summarise the barriers identified during this research.

Dental outreach is a hectic and busy environment lacking in continuity. Dental students are amenable to the lack of continuity when they are motivated to carry out dental care. The addition of clinical research into this environment highlighted the main barriers:

- Attitude and motivation of dental students towards carrying out clinical research studies
- Lack of continuity between treating dental student and outreach patients
- Lack of continuity between the clinics (layout and where to find things)
- Lack of staff continuity within some outreach clinics, both supervisory and nursing
- Lack of altruism from some dental students
- Lack of time on outreach clinics for research paperwork completion
- Dental outreach patients attend for repeat appointments reducing the pool of available potential participants

There were also a number of minor barriers which could likely be overcome:

- Time for approvals - this could be overcome by organising the research in advance of the year group so that everything would be in place for them starting in September

- Geography of the outreach clinics - this could be overcome by selecting one or two outreach clinics to take part in future projects
- Level of support required - this could be overcome by improved training and increasing support for clinics in the recruitment phase of the research

The mind-set and lack of engagement of some outreach staff and a small number of the dental students, unfortunately influenced the year group and proved to be a substantial barrier towards this particular research study. The findings from the post study exploration would indicate that this would not necessarily be the case for any future studies in outreach, provided that the studies were appropriately managed. Changes to the place of clinical research within the dental curriculum and a more enthusiastic introduction to future studies in dental outreach could be expected to help overcome this.

The challenge of continuity of care between treating dental student and outreach patients and lack of altruism from dental students was a barrier at the recruitment phase. However, this could be overcome by mailing out information to participants or involving receptionists in the process. This lack of continuity proved to be an advantage when it came to reviewing participants and blinding the study.

The lack of continuity between the clinics could be overcome by having a dedicated research nurse (perhaps with a research badge for easy identification) or member of staff and a specific area laid out with research materials clearly obvious to dental students when they arrive at the clinics. It would then be clear to the students where to go and who to ask for help.

Digitisation of the research records could help with the paperwork management challenges. The repeat appointments resulted in small numbers of participants available for recruitment however this could be overcome by opting for smaller scale studies in outreach with shorter review times.

10.11 Identified Facilitators Towards Clinical Research in Dental Outreach

The dental students were positive about dental outreach as a research environment. During DOOHS a number of facilitators towards carrying out clinical research in dental outreach were identified:

- Clinical dental director support (10.11.1)
- Dental outreach supervisors (10.11.2)
- Dental outreach patients (10.11.3)
- Dental students (10.11.4)
- Dental outreach nurses (10.11.5)
- University links and support from the dental school (10.11.6)
 - Supportive of the incorporation of clinical research into the curriculum
 - Links with research organisations such as TAHSC and SDPBRN to assist
 - Dental outreach day

These facilitators will now be discussed.

10.11.1 Clinical Dental Director Support

The support from clinical dental directors was an essential facilitator for clinical research in dental outreach. Tayside had a Clinical Dental Director who had completed a PhD and was the most supportive, offering a generous amount of time for staff to be trained compared to the other clinics. NHS Tayside additionally allowed and use of dental chairs and nurses during dental student holidays. NHS Fife were similar but did not give as much supervisor time for training. Clinical Dental Directors from all NHS boards saw clinical research as important and agreed for the approvals for the research.

10.11.2 Dental Outreach Supervisors

Dental outreach supervisors agreed to be trained in clinical research and on the whole were supportive of it in their clinic. Many of the outreach supervisors carried out additional work to facilitate the research during their lunch time. Staff supported the students on the clinic and encouraged the less enthusiastic students with clinical research procedures. Dental outreach supervisors in NHS Fife knew their patients well and could organise effectively those requiring recalls. They showed initiative during the study and made their own system of recalling research patients and keeping their own logs when the TAHSC provided logs were found to be unfit for purpose. The supervisors were good at communicating with the author and highlighting any problems along the way. The support and goodwill of outreach supervisors is essential to the delivery of research in the outreach clinic.

10.11.3 Dental Outreach Patients

Dental outreach patients are a previously unstudied cohort of patients. Research in outreach gave outreach patients an opportunity to become involved with clinical research studies. Dental outreach patients enjoyed being involved with DOOHS. They saw it as an opportunity to '*give something back*'. They gained more information about oral health care and were seen for additional appointments. They were happy to be recruited to a clinical study and to return for review appointments.

Outreach patients were found to have a high rate of dental disease as many had not received dental care for some time. This was considered to be beneficial for clinical research.

The ability to recruit patients from across all NHS boards was also considered to be of benefit to clinical research.

10.11.4 Dental Students

Dental students were found to have the necessary skills to consent dental patients to clinical research studies. By the final year, students additionally have the skills to take accurate measures and deliver an intervention to the participants. Students kept their groups blinded and successfully allocated participant IDs to the participants in the study. They completed the CRFs with minimal errors and managed to carry out additional items of dental care alongside clinical research.

10.11.5 Dental Outreach Nurses

Dental outreach nurses were found to be the primary facilitator for clinical research in dental outreach. The nurses knew their outreach patients well. They kept track of research materials, knew who had and hadn't received patient information. They gave the students the research materials and they required and encouraged them with the research procedures. Dental nurses at two of the sites ran the recall log sheets and were responsible for organising further appointments for the participants. Additionally, they got to know the dental students well and were good at communicating any problems back to the research team. Dental nurses improved the research environment and general organisation. Dental nurse support is fundamental to clinical research in dental outreach.

10.11.6 University Links and Support From the Dental School

The links that dental outreach has with the University of Dundee provided essential support during the research process.

The dental school gave permission for the final year dental students be involved in the clinical research and considered it to be acceptable for students to carry out research during outreach attachments and gave approval for clinical research to be part of the curriculum for that final year.

During the initial stages of research, SDPBRN provided advice and support from their experienced research team to assist in development the protocol. This enabled the protocol and questionnaires to be developed to a standard which was acceptable to the ethics process. This saved time. TAHSC gave valuable advice regarding involving dental students with clinical research. They were able to advise that dental students could reasonably carry out consent procedures for clinical research studies with supervisor support. They also advised that students involved in clinical research would be seen as collaborators and that as such they would need to have GCP and protocol training and that each student would be required to submit a research CV.

When the ethics committee met, researchers from SDPBRN provided the advice that the author and supervisor should attend the committee. This attendance at the ethics meeting allowed questions to be directly answered on the day which saved the research process precious time and enabled the NHS R&D applications to go forward quickly.

Overall, the links with the University allowed the approvals applications to progress smoothly and ensured that any delays were not on the part of the researcher.

TAHSC advised on GCP training. They ran the initial GCP training for the dental students and although this went down poorly with the students much was learnt from this experience and it allowed the staff and future student training to be improved. TAHSC advised on site files and the conduct of research management with regards to site visits.

The regular communication with the University enabled the outreach clinics to keep in contact during DOOHS and advise the author of any problems. This link additionally allowed the author to be involved in student supervision on the clinics during DOOHS giving valuable insight into the outreach clinics during a clinical study.

Chapter 11: Limitations of This Work and Final Conclusions

11.1 Aim

The aim of this research was to investigate the feasibility of clinical research in dental outreach clinics.

This was achieved through a pilot clinical research study in dental outreach clinics investigating the effectiveness of oral hygiene instruction delivered to dental outreach patients. The barriers, facilitators, advantages and disadvantages of the outreach environment in supporting clinical research studies were addressed through:

- focus groups with stakeholders and students
- questionnaires to participants, outreach staff and final year dental students following their involvement with research
- direct observations by the author during the clinical research study

11.2 Limitations

The research was conducted in Scotland and therefore the research approval process findings reflect the Scottish experience. There may be differences in research ethics and NHS R&D approval procedures for the rest of the UK.

The clinics where the research was conducted were all linked to the University of Dundee. Although six clinics were included in this study, there may be differences in the set up of outreach clinics elsewhere which may result in the findings from this thesis requiring adaptation for research delivery. Training of staff and the amount of support required to conduct clinical studies in outreach are two such areas.

DOOHS investigated oral hygiene instruction effectiveness. As such this research is limited to the ability of students to deliver a variation on what they have been taught by the dental curriculum (in this case oral hygiene instruction). The students were

familiar with the measurements used and these were in line with teaching practices at Dundee Dental School at the time. It would be likely that students could easily be taught new measures but this particular study was limited to the utilisation of existing student practices for clinical research. If new measures were to be taught to a student group, additional training time would be required and the particular year group of students carrying out the research and timing within the curriculum would require careful consideration.

DOOHS was only delivered by Dundee University final year dental students. In addition, therapy students attend outreach attachments. Future studies in outreach could consider approaching the Schools of Oral Health Science. This would enable dental therapy students from Dundee University and/or The University of Highlands and Islands to be included in research collaboration and potentially increase participant recruitment. Dental therapy students from both of these institutions regularly work with University of Dundee dental students in outreach clinics. However, care should be taken to ensure clinical teaching and practise is aligned.

The role of clinical research in the undergraduate curriculum requires consideration. At the beginning of DOOHS, dental undergraduates did not see clinical research as part of primary care dentistry. Although they indicated that their involvement with DOOHS had enabled them to gain an insight into clinical research, very few were of the opinion that they would wish to carry out clinical research in the future. This view that clinical research is not part of 'normal dentistry' needs to be challenged. The students piloting clinical research in dental outreach through the implementation of DOOHS did in fact gain a unique insight into clinical research.

The dental outreach clinics provided a suitable platform for clinical research. Their links to the university ensured support was in place for clinical research studies to be carried out. Even with this help and support, setting up and running DOOHS took a considerable amount of time and effort. It placed additional stress on the clinics and their supervisors. Dental outreach supervisors required additional support in order to supervise clinical studies in outreach.

The support and enthusiasm from dental outreach nurses was fundamental to the feasibility of clinical research in dental outreach clinics.

Research application processes require streamlining as no doubt many potential researchers would be put off by the vast quantity of paperwork required in order to set up clinical research studies.

DOOHS was run as a multi-centre trial. Processes could have been simplified if outreach clinics in only one or two NHS boards had been selected to take part in the research. Although this would have reduced the number of participants recruited, it would have enabled research resources to be targeted to those particular clinics instead of being spread thinly between many. If research in dental outreach were to be carried out again, it would be the recommendation of this author that NHS Tayside and NHS Fife are chosen to carry out the clinical research study. In particular Kirkcaldy and Springfield outreach clinics should be included.

11.3 Impact of This Work

The piloting of clinical research in dental outreach through the Dental Outreach Oral Hygiene Study has had some impact nationally:

- Dental outreach clinics were included for data collection for the HOPSCOTCH pilot study (Conway et al. 2016)
- The HOPSCOTCH study utilised research nurses to collect data within the dental outreach clinics
- One of the dental nurses collaborating with DOOHS gained a research nurse position within SDPBRN
- Some dental students included their collaborated with DOOHS as research experience in job applications. This experience gained them an extra point towards interview shortlisting for postgraduate training positions

11.4 Conclusions

The pertinent findings of this thesis are:

- Attitudes of dental students concerning the place of clinical research in primary care dentistry needs to be addressed by the curriculum
- Dental students and supervisors wish involvement in research development, not just in the delivery of research
- Dental students can carry out clinical research under supervision
- Approvals can be gained for non-invasive clinical research studies in outreach clinics
- Good Clinical Practice training for clinical studies in dental outreach should be delivered by those used to teaching clinical dentistry and made relevant for the clinics
- Dental outreach patients are happy to participate in clinical research studies during dental appointments and will return for review visits
- Paperwork needs to be minimalised for outreach clinics, ideally data would be collected digitally
- Dental nurses are essential to the successful delivery of clinical studies in dental outreach clinics

Overall, with hard work and collaboration it is feasible to carry out clinical research studies in dental outreach clinics.

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Appendix 1

Literature Review Search Structure

Literature search

MEDLINE (OVID) SEARCH STRATEGY

1. community outreach/
2. community based participatory research/
3. (outreach\$ or out-reach\$ or "out reach\$").mp.
4. (community-based or "community based").ti,ab.
5. (community adj5 relation\$).mp.
6. ("extra mural\$" or extra-mural\$ or extramural\$).ti,ab.
7. ("primary care" adj5 (attachment\$ or placement\$)).ti,ab.
8. "pipeline program\$".ti,ab.
9. or/1-8
10. Education, dental/
11. exp Students/
12. (student\$ or undergraduate\$ or "under graduate\$" or under-graduate\$ or postgraduate\$ or post-graduate\$ or graduate\$).ti,ab.
13. 11 or 12
14. (dental or dentist\$ or "oral health" or "oral hygiene").ti,ab.
15. Dentistry/
16. 14 or 15
17. 10 or (13 and 16)
18. 9 and 17
19. clinical\$.ti,ab.
20. 18 and 19

168 records

EMBASE (OVID) SEARCH STRATEGY

1. (outreach\$ or out-reach\$ or "out reach\$").ti,ab.
2. (community-based or "community based").ti,ab.

3. (community adj5 relation\$).ti,ab.
4. ("extra mural\$" or extra-mural\$ or extramural\$).ti,ab.
5. ("primary care" adj5 (attachment\$ or placement\$)).ti,ab.
6. "pipeline program\$".ti,ab.
7. (student\$ or undergraduate\$ or "under graduate\$" or under-graduate\$ or postgraduate\$ or post-graduate\$ or graduate\$).ti,ab.
8. (dental or dentist\$ or "oral health" or "oral hygiene").ti,ab.
9. clinical\$.ti,ab.
10. or/1-6
11. 7 and 8
12. 10 and 11 and 9

104 records

COCHRANE LIBRARY (OVID) SEARCH STRATEGY

1. community outreach/
2. community based participatory research/
3. (outreach\$ or out-reach\$ or "out reach\$").ti,ab.
4. (community-based or "community based").ti,ab.
5. (community adj5 relation\$).ti,ab.
6. ("extra mural\$" or extra-mural\$ or extramural\$).ti,ab.
7. ("primary care" adj5 (attachment\$ or placement\$)).ti,ab.
8. "pipeline program\$".ti,ab.
9. or/1-8
10. Education, dental/
11. exp Students/
12. (student\$ or undergraduate\$ or "under graduate\$" or under-graduate\$ or postgraduate\$ or post-graduate\$ or graduate\$).ti,ab.
13. 11 or 12

14. (dental or dentist\$ or "oral health" or "oral hygiene").ti,ab.
15. Dentistry/
16. 14 or 15
17. 10 or (13 and 16)
18. 9 and 17
19. clinical\$.ti,ab.
20. 18 and 19

2 records

CINAHL (EBSCO) SEARCH STRATEGY

- S1 TX (outreach* or out-reach* or "out reach")
- S2 TX (community-based or "community based")
- S3 TX (community N5 relation*)
- S4 TX ("extra mural*" or extra-mural* or extramural*)
- S5 TX ("primary care" N5 attachment*) OR TX ("primary care" N5 placement*)
- S6 TX (pipeline program*) OR TX ("primary care" N5 placement*)
- S7 TX S1 or S2 or S3 or S4 or S5 or S6
- S8 TX (student* or undergraduate* or under-graduate* or postgraduate* or post-graduate* or graduate*)
- S9 TX (dental or dentist* or "oral health" or oral hygiene*)
- S10 TX S8 and S9
- S11 TX clinical*
- S12 TX S7 and S10 and S11

60 records

Appendix 2

Literature Search Results Table

Author(s)	Year	Title	Journal	Country where research conducted	Notes on the research	Main findings
Abuzar MA et al	2009	Development of a rural outplacement programme for dental undergraduates: students' perceptions	European Journal of Dental Education	Australia	Educational research	Benefits to dental students, worthwhile attachment and encouraged students to apply for jobs in rural practices
Aggarwal VR et al	2011	Proposed career pathway for clinical academic general dental practitioners	Primary Dental Care	UK	Discussion paper: modernising medical careers.	Encouraging general practitioners to research and academia. Increase dental academics and support outreach clinics to reflect primary dental care.
Andersen RM et al	2005	Pipeline, profession, and practice program: evaluating change in dental education	Journal of Dental Education	USA	Survey of dental schools in the pipeline programme.	Increase in ability to care for diverse patient groups. Worthwhile experiences for students.
Arevalo O et al	2011	Measuring clinical productivity in community-based dental education	Journal of Dental Education	Puerto Rico	Educational research. 158 students over 3 years in placements.	Using site productivity as a tool in order to justify and select placements.

		programs				
Atchison KA et al	2011	Comparison of extramural clinical rotation days: did the Pipeline program make a difference?	Journal of Dental Education	USA	Pipeline programme to increase minority students in dental education. Students spend up to 8 weeks in extramural settings in final year. Optional.	More likely to attend extra mural attachments if orientated towards service.
Atchison KA et al	2009	Community-based clinical dental education: effects of the Pipeline program	Journal of Dental Education	USA	Pipeline supplement report.	Overview of pipeline project
Ayers CS et al	2001	U.S. and Canadian dental school involvement in extramural programming	Journal of Dental Education	USA	Report into extramural programming across USA and Canadian dental schools.	Increasing amounts of time spent during courses from first to final years. Simpler treatments carried out but large numbers of these treatments. Educational benefits.
Ayers CS et al	2003	A comparison of private and public dental students' perceptions of extramural programming	Journal of Dental Education	USA	Survey based research looking at intension to work in private versus public dental services.	Extra mural programmes increase interest in public dental services.

Bhayat, A., Mahrous, M.S.	2012	Impact of outreach activities at the College of Dentistry, Taibah University	Journal of Taibah University Medical Sciences	Saudi Arabia	Students visits to primary school and rehab centre to offer nutritional and oral health care advices	Attending outreach attachments reported to had a positive effect on the students and contribute to personal growth and increase their social responsibility
Bailit H	2010	Financial impact of community- based dental education	Journal of Dental Education	USA		Extramural attachments increase student productivity, additional income for extramural clinics. Additional advantages.
Bailit HL & Formicola AJ	2010	About the Dental Pipeline Program	Journal of Dental Education	USA	Overview about the Pipeline programme.	Not research in outreach but provides information about the Pipeline project.
Bailit H	2010	Organization and management of community-based dental education programs: an overview from the dental Pipeline program	Journal of Dental Education	USA	Introductory paper to US pipeline project.	Benefits of access to dental services for patient groups, enriched education for dental students.
Bailit H et al	2007	Financing clinical dental education	Journal of Dental Education	USA	Financial research into outreach clinics in US, not relevant to this review.	Not relevant to this review
Bailit H et al	2009	The Dental	Journal of	USA	Pipeline project	See overall pipeline review paper.

		Pipeline program: the National Program Office perspective.	Dental Education		continued.	
Bailit H et al	2005	The origins and design of the Dental Pipeline program	Journal of Dental Education	USA	Origins of the pipeline programme. 15 dental schools involved.	Increase time students spend in extramural clinics treating populations requiring care; provide teaching courses to prepare students for the experience; recruit dental students from the minority populations. Ensure a sustainable programme.
Baumeister SE et al	2007	What influences dental students to serve special care patients?	Special Care Dentistry	USA	Educational research	Influence of extramural attachments to students social conscious attitudes. Beneficial.
Bartlett, DW, Woolford, M	2003	Team training at an outreach dental unit.	The European journal of prosthodontics and restorative dentistry	UK	Educational research questionnaire	Benefits of dental team working and dental nurses in outreach
Bean CY	2011	Community-based dental education at the Ohio State University: the	Journal of Dental Education	USA	Development of extramural attachments in US.	Increase of dental services and emergency services for populations through these attachments

		OHIO Project				
Bean CY et al	2007	Comparing fourth-year dental student productivity and experiences in a dental school with community-based clinical education	Journal of Dental Education	USA	Productivity of dental students in hospital and community clinics.	42 days in community 26,882 procedures versus 28680 procedures in 93 days in dental school. Higher productivity in outreach.
Berg R et al	2010	Impact of the University of Colorado's Advanced Clinical Training and Service (ACTS) Program on dental students' clinical experience and cognitive skills, 1994-2006	Journal of Dental Education	USA	12 year data for fourth year student productivity.	Self-assessed competency increased.
Blinkhorn FA	2002	Evaluation of an undergraduate community-based course in Family Dentistry	European Journal of Dental Education	UK, Salford	Student expectations during attachments.	Communication skills and confidence increased. Run as family dentistry course.

Bohaty BS et al	1992	Pediatric dental education and community service: a combined approach	Journal of Dentistry for Children	USA	Paediatric attachments in community.	Provides experience for students and services for community.
Butters JM & Vaught RL	1999	The effect of an extramural education program on the perceived clinical competence of dental hygiene students	Journal of Dental Education	USA	Dental hygiene students.	Increase in student perception of self- competence.
Cannavina G et al	2004	Evaluation of video- conferencing as a means to facilitate outreach and work based learning	Work Based Learning in Primary Care	UK	Video conferencing to teach problem solving.	Not relevant to this review
Chavez EM & LaBarre EE	2004	A predoctoral clinical geriatric dentistry rotation at the University of the Pacific	Journal of Dental Education	USA	Educational research	Increase experience through attachments.

		School of Dentistry				
Cinotti WR et al	1999	T1 - Community-based dental programs: University of Medicine and Dentistry of New Jersey-New Jersey Dental School	Journal of Dental Education	USA	Managerial issues around extra mural attachments.	Not relevant to this review.
Conway, D.I. et al	2016	Human Papilloma Virus (HPV) Oral Prevalence in Scotland (HOPSCOTCH): A Feasibility Study in Dental Settings	PLoS ONE 11(11),e0165847	UK	Pilot study involving questionnaires and saliva samples	Population investigation pilot. Dental outreach utilised a research nurse for recruitment. Outreach was a suitable platform to include for research
Craddock HL	2011	An evaluation of student, patient and practitioner experience of general dental practice placements	British Dental Journal	UK, Leeds	Student patient and practitioner experiences of outreach.	Students reported difference between outreach and GDP service. Teamwork experience, positive clinical experience for students. Benefits for practitioner teams.

Craddock HL	2008	Outreach teaching - the Leeds experience: reflections after one year	British Dental Journal	UK	Discussion report	Benefits to students include exposure to different patient groups, improvement in time management.
Crall JJ et al	2009	The Pipeline program at Boston University Goldman School of Dental Medicine.	Journal of Dental Education	USA	USA pipeline programme supplement, see previous pipeline.	USA pipeline programme supplement, see previous pipeline.
Cure R	2009	Education for the dental team: make your practice a centre of learning excellence.	Primary Dental Care: Journal of the Faculty of General Dental Practitioners	UK	Changing needs of dental curriculum within Europe.	Outreach attachments, education into primary care to improve learning of both student and practice.
Daher et al	2012	Dental students' perceptions of community-based education: A retrospective study at a dental school in Brazil.	Journal of Dental Education	Brazil	Students submitted a report from their experiences from paediatric dental attachments.	Positive experiences in first semester attachments when performing dental treatment themselves.
DeAngelis S	2001	Establishing	Journal of	USA	Dental hygiene	Development of skills and appreciation

& Warren C		community partnerships: providing better oral health care to underserved children	Dental Hygiene		students; community attachments.	of oral disease in communities.
DeCastro JE et al	2005	Clinical competence of graduates of community-based and traditional curricula	Journal of Dental Education	USA	Comparison of students in community orientated dental education (CODE) and traditionally educated students.	Students displayed higher grades in the restorative section and higher clinical productivity and passed the same competencies as the traditionally educated students.
DeCastro JE et al	2003	Alumni perspectives on community-based and traditional curricula	Journal of Dental Education	USA	Community orientated dental education alumni versus traditional alumni questionnaire research. Educational and attitudes investigated.	Educational and attitudes investigated.
Eaton, KA et al	2006	'Schools without walls?' Developments and challenges in dental outreach teaching - report of a recent symposium	European Journal of Dental Education	UK	Summary paper on outreach themes	Not research in outreach so not relevant to this review but covers findings from other papers such as benefits of outreach to dental students

Elkind A	2002	Outreach teaching: is this the future for dental education?	British Dental Journal	UK	Report of workshop, outlining the benefits of outreach teaching to groups involved:	Contact with 'real' patients. Skill development: teamwork, time management, communication. Variety of patients and procedures, contact with healthcare team. Wider view of dentistry. Links with community and academia. Motivation of staff and service. Valuable transition to practice.
Elkind A et al	2005	Developing dental education in primary care: the student perspective	British Dental Journal	UK	Educational research: questionnaire based for dental students.	Students increased confidence in diagnosis, treatment planning, simple restorations, communication, and management of patients, time, and resources
Elkind A et al	2005	Patients treated by dental students in outreach: The first year of a pilot project	European Journal of Dental Education	UK	Patient care and demographics collected from notes and by patient questionnaire. .	Students able to carry out a full range of procedures on this group of patients. Patients had not been able to register with dentists out with the clinic
Elkind A et al	2006	Service quality implications of dental undergraduate outreach teaching for Primary Care Trusts in England, UK	Community Dental Health	UK	Patient views of outreach.	Mainly attend as the clinic as it is local, most have not received care for 2yrs beforehand. Quality of care received rated highly (96%). Majority would return to clinic in future.

Elkind A et al	2007	The use of outreach clinics for teaching undergraduate restorative dentistry	British Dental Journal	UK	Semi structured interviews and meetings	Teaching isolated and stressful, steep learning curve for teaching staff. Identifies characteristics required for outreach teachers. Outlines academic concerns over teaching quality.
Eriksen HM et al	2011	Evaluation of a dental outreach teaching programme	European Journal of Dental Education	Norway	Educational.	Training/educating outreach teachers vital. Students gain wide range and volume of experience and gain maturity.
Evans CA	2008	The role of dental schools in the issues of access to care	Journal of the American College of Dentists	USA	Pipeline programme.	Students spend 60 days in 17 sites providing care during their 4 th year. They have to qualify for the experience and report it.
Formicola AJ	2002	A new format for dental education	Journal of the American College of Dentists	USA	Development of dental curriculum in US increasing outreach as part of restructuring the curriculum.	Discussion paper
Formicola AJ & Bailit	2012	Community Based Education: History, Current Status, and Future	Journal of Dental Education	USA	Senior students spending more time in community based attachments. Now core to the curriculum	Discussion paper
Fox Karen	2011	Dental student	American	USA		Issues around students carrying out

		outreach eyed: new ADA policy emphasizes ethics, supervision in volunteer settings.	Dental Association News			procedures they haven't been trained to do with the idea that doing something is better than nothing in remote areas. Policy from ADA to ensure students adequately supervised.
Harris, M., Wilson, J.C., Holmes, S., Radford, D.R.	2017	Perceived stress and well-being among dental hygiene and dental therapy students	British Dental Journal	UK	Educational questionnaire research	Students reported stress but that they were functioning as individuals.
Heitke SB	1984	Marquette University's extramural clinical program	Journal of Dental Education	USA	Students attend 6 week outreach attachments to gain experience of different patient groups.	Experience increased
Hewlett ER et al	2009	The Pipeline program at the University of California, San Francisco, School of Dentistry.	Journal of Dental Education	USA	Review of US pipeline programme, San Francisco.	Review paper
Hewlett ER et al	2009	Revisions to dental school curricula: effects of the Pipeline	Journal of Dental Education	USA	Educational research	Benefits of the pipeline programme, including experiential learning and treatment of diverse groups.

		program.				
Hien LTT et al	2008	Effectiveness of a capacity-building program for community leaders in a healthy living environment: a randomized community-based intervention in rural Vietnam.	Health Promotion International	Vietnam	Community based RCT for healthy living training intervention.	Community leaders were effectively trained to implement promotion of healthy living.
Hind V et al	2009	Developing a primary dental care outreach (PDCO) course-- part 1: practical issues and evaluation of clinical activity	European Journal of Dental Education	UK, Newcastle	Undergraduates attend rotations over two year period.	Issues in setting up with teaching quality, timetabling, training staff and communication. Clinical activity data. This group also ran SCOTs in outreach successfully.
Hind V et al	2009	Developing a primary dental care outreach (PDCO) course-- part 2: Perceptions of	European Journal of Dental Education	UK, Newcastle	Educational questionnaire research looking at self-reported confidence and skills and general outreach experience information	Reported increase in confidence and skills in treating child and adult patients in outreach

		dental students				
Holmes RD et al	2011	Developing an assessment in dental public health for clinical undergraduates attending a primary dental care outreach programme	European Journal of Dental Education	UK, Newcastle	Use of outreach to teach social awareness and impact of social history. Students completed assignments detailing importance of social history in relation to treatment planning.	Increased reported understanding of obtaining and relevance of patient social history
Hryhorczuk C et al	2008	A model for selection and assessment of community-based sites for dental students' extramural clinical experiences	Journal of Dental Education	USA	Discussion paper covering the development of the pipeline project.	Not relevant to this thesis
Hunter ML & Chaudhry U	2009	Paediatric dentistry in outreach settings: an essential part of undergraduate curricula?	European Journal of Dental Education	UK Cardiff	Educational research into experience gained in paediatric dentistry within outreach settings using student logbook data.	Experience increased by attending outreach attachments

Hunter, M.L., Oliver, R., Lewis, R.	2007	The effect of a community dental service outreach programme on the confidence of undergraduate students to treat children: a pilot study.	European Journal of Dental Education	UK Cardiff	Educational research questionnaire	Confidence increased after attending outreach attachments.
Huynh-Vo L et al	2002	Investigating the potential for students to provide dental services in community settings	Journal (Canadian Dental Association)	Canada	Interview research revealing support for outreach in community settings.	Largest barrier funding. Sites would welcome both dental and hygiene students.
Johnson I et al	2012	Undergraduate students' experiences of outreach placements in dental secondary care settings	European Journal of Dental Education	UK	Questionnaire following 1 week placement	Positive educational benefit cited by most but not all students
Jones DL et al	2011	The evidence-based dentistry initiative at Baylor College of Dentistry	Texas Dental Journal	USA	Reference obtained by email from author.	Evidence based dentistry threaded through the curriculum with assignments and coursework. Students don't carry out clinical research studies but do carry out research projects with faculty.

Joury, E	2016	Community-based learning in a challenging context: The development and evaluation of an outreach dental public health programme in Damascus University, Syria	European Journal of Dental Education	Syria	Students carried out DPH research in a school setting as an elective activity Data collected by questionnaire	Learnt new skills Professional and personal growth Utilised schools as no other outreach settings available.
Kassebaum DK	2004	The dental curriculum at North American dental institutions in 2002-03: a survey of current structure, recent innovations, and planned changes	Journal of Dental Education	USA	Survey, current curriculae and integration of outreach/community attachments.	Schools looking to increase exposure to community based dental care.
Kerosuo E et al	2001	Report on the development of a new dental curriculum at Helsinki	European Journal of Dental Education	Finland	Integration with medics to understand disease in the community pre clinical stages.	Attitudes, interpersonal skills, teamwork.
Kuthy RA et	2007	Students' opinions	Journal of	USA		Extra-mural attachments increased

al		about treating vulnerable populations immediately after completing community-based clinical experiences	Dental Education			students' consideration towards treating vulnerable populations in their future careers.
Kuthy RA et al	2010	Dental students' perceived comfort and future willingness to treat underserved populations: surveys prior to and immediately after extramural experiences	Special Care in Dentistry	USA		Extra-mural attachments increased students' comfort to treat vulnerable populations in their future careers.
Lautar CJ et al	2005	Preparing students for alternative practice: rewards and barriers in service learning.	Journal of Dental Hygiene	USA	Educational research placing hygiene students in community attachments.	Not relevant to this thesis
Lekic PC et al	2000	A program to ensure adequate	Journal of Dental	Canada	Educational research increasing paediatric	Not relevant to this thesis

		clinical experience in undergraduate paediatric dentistry	Education		experience.	
Lennon MA	2007	Expanding dental undergraduate clinical outreach programmes into general dental practice	Community Dental Health	UK, Sheffield	Outreach development	Not relevant to this thesis
Lindsay Hunter, M., Oliver, R., Lewis, R.	2007	The effect of a community dental service outreach programme on the confidence of undergraduate students to treat children: A pilot study	European Journal of Dental Education	UK, Cardiff	Educational research by questionnaire	Increased confidence by students after outreach placements
Lloyd PM	2007	Reaching out to meet the needs of many	Northwest Dentistry	USA	Advantage of outreach to underserved populations.	Outreach prepares undergraduates better for practice and provides dental care to communities who otherwise would have difficulty accessing care
Lynch CD et al	2011	Evaluation of a community-based clinical teaching	British Dental Journal	UK, Cardiff	Educational research by questionnaire, investigating therapist	Beneficial and students supportive of the attachments.

		programme by current and former student dental therapists and dental hygienists: a pilot investigation			and hygiene students' experience of outreach.	
Lynch CD et al	2010	Student perspectives and opinions on their experience at an undergraduate outreach dental teaching centre at Cardiff: a 5-year study	European Journal of Dental Education	UK, Cardiff	Educational research by questionnaire. Dental students' outreach experiences.	Enthusiasm for outreach, nursing support, outreach staff, confidence building and learning experience close to practice
Lynch CD et al	2010	Students' clinical experience on outreach placements	European Journal of Dental Education	UK, Cardiff	Comparison of data of clinical work carried out on outreach and hospital	Much more experience in outreach and more in GP outreach rather than CDS
Lynch CD et al	2010	Effect of community-based clinical teaching programs on student confidence: a	Journal of Dental Education	UK, Cardiff	Educational research. Questionnaire investigating reported student confidence on performing range of clinical treatments.	Students reported higher confidence in carrying out clinical treatments after attending outreach attachments.

		view from the United kingdom				
Lynch CD et al	2010	Evaluation of a U.K. community-based clinical teaching/outreach program by former dental students two and five years after graduation	Journal of Dental Education	UK, Cardiff	Educational research by questionnaire to former students.	Outreach experience reported to be beneficial to future dental career. Nursing support, atmosphere, staff all cited as beneficial.
Lynch CD et al	2011	Preparing dental students for careers as independent dental professionals: clinical audit and community-based clinical teaching	British Dental Journal	UK, Cardiff	Training in clinical audit embedded into outreach teaching at Cardiff.	This is closest to clinical research into dental outreach. Paper forms a report on the audits carried out in the outreach facility at Cardiff.
Lynch CD et al	2011	Evaluation of a community-based clinical teaching programme by current and former student	British Dental journal	UK, Cardiff	Questionnaire based research involving dental therapy students about outreach and working as a team.	Positive about outreach attachments and their career, increased confidence and experience. Prepares students for primary care.

		dental therapists and dental hygienists: A pilot investigation				
Maguire A et al	2009	Developing a primary dental care outreach (PDCO) course-- part 2: perceptions of dental students	European Journal of Dental Education	UK, Newcastle	Educational research questionnaire investigating students' reported confidence skills and team working after time spent in outreach.	Majority students report outreach as beneficial to professional training and development.
Martin N et al	2010	Factors influencing the quality of undergraduate clinical restorative dentistry in the UK and ROI: the views of heads of units	British Dental Journal	UK, Sheffield	Survey carried out over the 14 UK dental schools.	Outreach clinics increase the undergraduates' clinical experience however this is reduced when they work in pairs.
Mascarenhas AK	2011	Community-based dental education at Boston University	Journal of Dental Education	USA	Educational research.	Students report increased self-confidence, patient management skills, and technical skills after outreach attachments. Outreach increases access to dental care for local communities.
Mascarenhas	2007	Evaluating	Journal of	USA	Educational research.	Longer outreach (externships) increases

AK et al		externship programs: impact of program length on clinical productivity	Dental Education			clinical confidence efficiency and skill as more complex procedures may be undertaken towards the end of longer attachments.
Mashabi S & Mascarenhas AK	2011	Impact of community externships on the clinical performance of senior dental students	Journal of Dental Education	USA		Increased clinical productivity of students after extra mural attachments.
McQuistan MR et al	2008	Dentists' comfort in treating underserved populations after participating in community-based clinical experiences as a student	Journal of Dental Education	USA	Questionnaire to practicing dentists who had attended extra mural attachments while in training.	Benefits etc
Miller SL & Heil J	1976	Effect of an extramural program of dental care for the special patient on	Journal of Dental Education	USA		Failure of course, inappropriately planned and developed. Attitudes not addressed

		attitudes of students				
Mofidi M et al	2003	Dental students' reflections on their community-based experiences: the use of critical incidents	Journal of Dental Education	USA	Educational research	Student: developed increased self-awareness, empathy, communications skills, and self-confidence. Critical incidents challenged assumptions and stereotypes, enhanced awareness of complexities of dental care, raised complex ethical dilemmas. a heightened professional identity reflection required for learning process.
Moreno JP	1991	The new Spanish curriculum: reasons for change	International Dental Journal	Spain	Educational research.	Early integration to clinic and to community.
- Nandakumar C & Robinson PG	2011	Teaching dental public health to undergraduates using community profiles and patient case studies	Community Dental Health	UK	Educational research Impact of environment on patient's health.	Getting more out of outreach.
Nicolas, E., et al	2009	Clermont-Ferrand dental school' curriculum: An appraisal by last-	European Journal of Dental Education	France	Educational research	Conclusions are to increase outreach experience but none of the research is about outreach

		year students and graduates				
Nitschke I et al	2008	Undergraduate education in gerodontology in Germany: the Leipzig Programme	Gerodontology	Switzerland	Educational research.	Social skills within the curriculum expanded through attachments in the mobile clinics.
Parrot, L. et al	2017	The perceptions of dental practitioners of their role as clinical teachers in a UK outreach dental clinic	British Dental Journal	UK	Survey research of dental students and outreach tutors	Outreach teachers feel isolated. Outreach teaching offers advantages to students.
Perez FA et al	2010	Comparison of clinical productivity of senior dental students in a dental school teaching clinic versus community externship rotations	Journal of Dental Education	USA	Educational research. 4 th year students.	Increased productivity of students in outreach but simpler procedures.
Piskorowski	2011	Development of a	Journal of	USA	Development of	Not relevant to this review as about

WA et al		sustainable community-based dental education program	Dental Education		outreach programme. Financial aspects of the partnership.	dental outreach development rather than research in outreach.
Radford DL, & Weld JA	2013	Micro-educational opportunities in outreach clinical dental education	British Dental Journal	UK	Opinion piece Intra and inter professional education	Discusses opportunities for final year students in different settings out with the dental school including conducting small group audits which enhances their skills
Radford DL. Et al	2014	The impact of integrated team care taught using a live NHS contract on the educational experience of final year dental students	British Dental Journal	UK		Students reported outreach placements to be useful in gaining experience in working as a team
Radford DR. & Hellyer, P.	2015	Dental students' perceptions of their experience at a residential outreach centre	British Dental journal	Radford DR. & Hellyer, P.	Educational questionnaire research	Dental students' perceptions of their experience at a residential outreach centre: realistic preparation for dentistry and feeling of 'belongingness' at the facility.
Radford, DR. et al	2015	Outreach Clinical Dental Education: the Portsmouth experience – a 4-year follow-up	European Journal of Dental Education	UK	Survey research of consecutive year groups of students identifying factors making outreach successful such as an	Bridging of the gap to foundation training and positivity about the attachment

		study			induction period	
D. R. Radford & P. Hellyer	2016	Belongingness in undergraduate dental education	British Dental Journal	UK	Educational questionnaire research	Feeling of 'belongingness' in outreach, positivity for attachments.
D. R. Radford & P. Hellyer	2017	Empowerment in a model of outreach undergraduate dental education	British Dental Journal	UK	Educational questionnaire research	Increase in self-awareness and self-confidence. Sense of being a dentist in the real world.
Rodd HD et al	2010	Undergraduate experience and self-assessed confidence in paediatric dentistry: comparison of three UK dental schools	British Dental Journal	UK Sheffield, Liverpool & Manchester	Educational research: Experience increased in core skills through placements in paediatrics.	Outreach attachments essential to clinical experience in paediatric dentistry
Romer M et al	1999	Predoctoral education in special care dentistry: paving the way to better access?	Journal of Dentistry for Children	USA	Educational research.	Students need more experience in paediatric dentistry
Sanders RM & Ferrillo	2003	A new school's perspective on	Journal of Dental	USA	Educational research	Introduced outreach earlier, students from 2 nd -5 th yr attend, carrying out

PJ Jr		clinical curriculum	Education			treatment to their level
Seymour GJ & Walsh LJ	2001	Dental education in Queensland I: the 1-3-1 model	SADJ	Australia		Outreach benefits: Improving health for communities and responsibility for it. Cost effective to both university and health service, extended clinical time. Diversity.
Smith M et al	2011	Outreach training: the special interest group's report	European Journal of Dental Education	UK Sheffield	Review article covering the outreach background, benefits and learning outcomes	Student increased confidence, teamwork, professionalism and competence after outreach attachments need for learning outcomes to be fulfilled during attachments
Smith M et al	2006	Student perspectives on their recent dental outreach placement experiences	European Journal of Dental Education	UK Sheffield	Semi structured interviews with students on either 10wk or 3wk attachments.	Benefits to students, confidence, teamwork, broadening experience, awareness of career choice. Supervision and preparation of students discussed.
Smith M et al	2006	Perspectives of staff on student outreach placements	European Journal of Dental Education	UK Sheffield	Qualitative interviews with outreach staff. Staff support for outreach.	Communication critical for outreach. Benefits to students, confidence and teamwork and supervision by a generalist.
Smith M et al	2006	A randomized controlled trial of outreach placement's	Journal of Dental Education	UK Sheffield	RCT educational research.	Outreach more effective at increasing students' confidence

		effect on dental students' clinical confidence				
Smith M et al	2009	RCT of the effects of block absence for outreach placements on dental students' finals grades	European Journal of Dental Education	UK Sheffield	RCT educational research.	No negative impact on finals grades. No significant difference.
Smith M et al	2010	The Sheffield outreach teaching programme	British Dental Journal	UK Sheffield	Discussion paper of programme development and the learning experiences of the students.	More management related not relevant to this review.
Smith M et al	2010	Students' clinical experience on outreach placements	European Journal of Dental Education	UK Sheffield	Educational research	Students cover twice as much clinical work on outreach compared to dental hospital clinics. Awareness of service delivery. Clinical skills develop. May be benefits in many different outreach placements for each student.
Strauss RP et al	2010	The impact of community-based dental education on students	Journal of Dental Education	USA	Benefits of outreach	Outreach attracts students to work in diverse areas. Opportunity to guide student values towards public service, ethics, engagement and health of public.
Taichman	2012	Where is	Journal of	USA	Survey research	One of the benefits of outreach

		leadership training being taught in U.S. dental schools?	Dental Education			attachments is that they provide a setting in which leadership skills can be developed
Thind A et al	2005	What determines positive student perceptions of extramural clinical rotations? An analysis using 2003 ADEA Senior Survey data	Journal of Dental Education	USA	Student questionnaire educational research.	Increase in social conscious, positivity towards providing dental care to specific minority patient groups. Positive experience.
Walley, S. et al	2014	Undergraduates self-reported clinical experience, confidence and perspectives of hospital and outreach paediatric dentistry: A three-year multi-centre evaluation	British Dental Journal	UK	Educational research, questionnaire based.	Dental students and staff looking at relationships and sense of belonging/multidisciplinary/team approach
Waterhouse P et al	2008	The development of a primary dental care	European Journal of Dental	UK Newcastle	Development and setting up of outreach course	Not relevant to this review

		outreach course	Education			
Watson DJ et al	2007	Issues in dental outreach teaching--an introduction for the primary care practitioner	Dental Update	UK Glasgow	Discussion/review paper	Increased educational exposure from outreach, development of outreach in certain areas of teaching (restorative) real life work environment.
Woronuk JI et al	2004	University of Alberta dental students' outreach clinical experience: an evaluation of the program	Journal (Canadian Dental Association)	Canada	Satellite programme, voluntary.	Students increased numbers of procedures. Carried out less prevention on subsequent rotations. May increase competence of graduates.
Zoitopoulos L et al	2007	Student evaluation of clinical outreach teaching in Community Special Care Dentistry.	Journal of Disability & Oral Health		Questionnaires over three years.	Six patients per day seen. positive comments about supervisors but cohort treated special care patients

Appendix 3

Stakeholders Standard Interview Schedule

Stakeholder Interview Questions

1. What is your role in outreach?
2. How long have you been involved in outreach?
3. Have you ever had the opportunity to be involved in clinical research?
4. Tell me a bit about your involvement.
5. How did you feel about the research experience?
6. Is research something you ever think about or that interests you?
7. What aspects of patient care do you think would benefit from a stronger evidence base, or from further research?
8. Are there any topics you feel would particularly suit the dental outreach environment?
9. What problems can you foresee in carrying out clinical research in dental outreach?
10. How do you feel about oral hygiene instruction as a topic, in general?
11. Do you feel oral hygiene instruction is a suitable topic for dental outreach?
12. Do you foresee any problems relating to oral hygiene instruction studies in dental outreach?
13. What aspects of the outreach clinics would be helpful to carrying out research, in general?
14. What aspects of the clinic would be helpful, specifically with regards to oral hygiene instruction?
15. Can you think of any disadvantages of clinical research in dental outreach for staff?
16. Can you think of any disadvantages of clinical research in dental outreach for students?
17. Can you think of any disadvantages of clinical research in dental outreach for patients?
18. Can you think of any disadvantages of clinical research in dental outreach for the service?
19. Can you think of any disadvantages of oral hygiene instruction based studies?
20. Can you think of any advantages of clinical research in dental outreach for staff?
21. Can you think of any advantages of clinical research in dental outreach for students?
22. Can you think of any advantages of clinical research in dental outreach for patients?
23. Can you think of any advantages of clinical research in dental outreach for the service?
24. Can you think of any advantages of oral hygiene instruction based studies?
25. Have you any other comments?

Appendix 4

Outreach Staff Research Introduction Presentation

This appendix can be accessed by using the QR Code below which will take you to the relevant presentation.



<https://uod.box.com/s/tsnd4ezcylwxspelvahbmsf34g4bz267>

Appendix 5

DOOHS Protocol

Study Protocol

Dental Outreach Oral Hygiene Study

Sponsor	<i>University Of Dundee</i>
Funder	
Funding Reference Number	
Chief Investigator	Dr A. Hall
EudraCT Number	n/a
CTA Number	n/a
MREC Number	10/S0501/43
ClinGov: Number	
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PROTOCOL APPROVAL

Dental Outreach Oral Hygiene Study

Signatures

By signing this document I am confirming that I have read, understood and approve the protocol for the above study.

Dr A.F. Hall

Chief Investigator

Signature

Date

K.N. Richardson

Principal Investigator

Signature

Date

Prof Peter Donnan

Trial Statistician

Signature

Date

LIST OF ABBREVIATIONS

BPE	Basic Periodontal Examination
GCP	Good Clinical Practice
RCT	Randomised Control Trial
TCTU	Tayside Clinical Trials Unit
SAE	Serious Adverse Event
CRF	Case Report Form
SuSAR	Suspected unexpected Serious Adverse Reaction

SUMMARY

Dental Outreach clinics in the East of Scotland are presently an unresearched primary care dental environment. These clinics have been set up as part of the Scottish Executives Action Plan (2005) to improve NHS dental services. They allow final year dental students the opportunity to treat 'real world' dental patients. Final year dental students from the University of Dundee currently carry out around 38,000 procedures each academic year on this patient group. These patients have often not received dental treatment for many years and display high levels of preventable disease, associated with poor oral hygiene.

At present there has been no clinical research carried out on this patient group; subsequently there is uncertainty around the most effective methods for managing the high levels of gum disease and tooth decay seen in this patient group.

Both gum disease and tooth decay are caused by dental plaque. There is substantive evidence that regular removal of dental plaque by patients, through simple oral hygiene procedures, can successfully prevent dental disease. However, there is still uncertainty around the best methods for **teaching** oral hygiene to patients. A Cochrane review confirmed evidence for using a psychological framework in the delivery of instruction. This was found to be effective in changing patient behaviour with regards to oral hygiene. However, the studies included in the review all had lengthy interventions which were not deemed practical for primary care dentistry. Clarkson et al investigated this further in their trial of simple psychological framework of 'Tell-Show-Do-Plan'. This intervention was run in both cluster trial and patient randomised control trial (RCT) methodology, and proved effective in changing behaviour of primary care dental practice patients.

Recently there has been interest in the role of biomarkers in patient control of gum disease. Biomarkers are indicators of disease that patients can observe and use to self monitor allowing them to subsequently modify their health behaviours as required. The biomarker of **bleeding** was used by Walsh in a small study and effectively improved patient adherence to interdental cleaning, although at that time the significance of bleeding being a potential biomarker was not clearly recognised. It was not until more recently that the term has come into routine use, mainly in other health care areas such as smoking cessation and diabetes control; both of these use biomarkers have been found to effectively increase patient self care behaviours.

This study aims to use the psychological framework developed by Clarkson, and will add in the use of the biomarker of bleeding into the plan phase of the framework. This method of teaching oral hygiene will be delivered as the intervention in dental outreach clinics, with the control group being the usual oral hygiene advice the final year students would give. It is hoped that this will prove to be an effective method for stabilising, through prevention, the high levels of disease seen on the outreach clinics.

The study also allows Dundee dental undergraduates the opportunity to participate in ethically approved clinical research for the first time. Until now there has been no opportunity in the dental undergraduate curriculum to gain the valuable knowledge and skills required to contribute to and participate in clinical research projects. It is hoped that by providing the opportunity to be involved in research at this early stage in their careers, that dental graduates will go forward with a positive attitude and interest in research. This would, we hope, increase primary care dental research in the future, improving evidence based practice.

1. INTRODUCTION

1.1 BACKGROUND

Scotland continues to suffer from preventable dental diseases such as tooth decay and gum disease. The Scottish Health Survey 2008 reported 30% of men and 27% women to self diagnose bleeding gums, a strong indicator of gum disease; these levels are higher when measured by general dental practitioners. Many of the methods of addressing oral health inequalities have focused on improving access to dental care. In part, this has been achieved through the building of new Dental Outreach clinics. These clinics provide free dental treatment delivered by final year dental students and carried out under dentist supervision. The clinics, which have now become widespread throughout Scotland, were constructed in areas with low NHS dental registration levels, under the direction of the NHS Action Plan for Improving Oral Health (Scottish Executive 2005). Subsequently, these clinics now provide treatment for patients with high levels of disease; many of whom have poor oral hygiene. As the clinics are set-up to provide only one course of treatment per patient, teaching of self maintenance and especially oral hygiene becomes absolutely essential for the longevity of treatment provided in the clinics.

1.2 RATIONALE

There have been many approaches to tackling the problem of poor oral hygiene at both a population level and also on an individual basis. Dental care providers give oral hygiene instruction as part of a preventive approach to treatment. However, there currently is no clear 'best practice' on how this instruction should be given. Indeed there is an ongoing Cochrane review of *One-to one oral hygiene instruction in the dental setting* (Soldani, Young et al. 2008) which is investigating benefits of providing oral hygiene instruction in the dental environment. The psychological side of teaching patients to change their toothbrushing behaviour has been the subject of a Cochrane review. This review (Renz, Ide et al. 2007) found only four studies meeting their inclusion criteria, none of which were suitable for primary care dentistry. With a focus on suitability of the psychological model for primary care, Clarkson et al, (Clarkson, Young et al. 2009) developed a five minute oral hygiene intervention. This psychologically framed, evidence based approach, prove to be effective in reducing plaque and bleeding in dental patients, when compared to a control group, over an 8 week period.

A recent review of periodontal treatment (Chapple 2009), also considered this psychological approach to behaviour change, highlighting the potential for the use of **biomarkers** in dentistry.

A biomarker is an indicator of disease that patients can self recognise. The integration of biomarkers has been used successfully in other health care areas such as diabetes control and smoking cessation. The first sign of gingival disease has a very clear biomarker, which is gingival bleeding. Patients are often aware their gums bleed, but may not be aware of the significance of this or how to effectively manage the bleeding. Gingival bleeding has been used in one small trial evaluating interproximal cleaning (Walsh, Heckman et al. 1985) and was found to be successful in improving home care compliance and gingival health.

The use of a validated psychological model enhanced with the use of biomarkers will be piloted in the dental outreach clinics by final year dental students in the form of a cluster randomised and controlled trial. It is hoped that this method will prove to be an effective method of improving the oral hygiene behaviour of dental outreach patients.

If this method proves effective, it will be rolled out in outreach clinics as standard practice; feeding back to influence teaching practice at Dundee Dental School. Clinical research in outreach will start to build an evidence base for treating this new group of primary care patients and allow dental undergraduates to gain valuable experience in clinical research.

2.1 OBJECTIVES

2.1.1 Primary Objective

To assess the effectiveness of oral hygiene instruction delivered within a psychological framework, with the inclusion of biomarker information, on the periodontal health of primary care dental outreach patients

2.1.2 Secondary Objectives

1. To assess the change in reported oral hygiene behaviours after this method of oral hygiene delivery.
2. To investigate the acceptability of clinical research to this new group of primary care patients and the participating students.

2.2 ENDPOINTS

2.2.1 Primary Endpoint

Reduction of gingival margin sites bleeding by 10%, which is clinically significant.

2.2.2 Secondary Endpoints

Outreach patients increasing their reported oral hygiene behaviours.

3. STUDY DESIGN

The study has been designed as a cluster randomised and controlled clinical trial. This will take place during the dental academic year. Final year dental students will be recruited to the study. They will subsequently record the measurements of dental plaque and gingival bleeding and deliver the intervention.

This methodology has been validated for the primary care dental environment and has been proven acceptable. The clustering design allows the dental students to be allocated purely to intervention or control group thus avoiding the possibility of contamination of the intervention, which would be difficult in a patient randomised design.

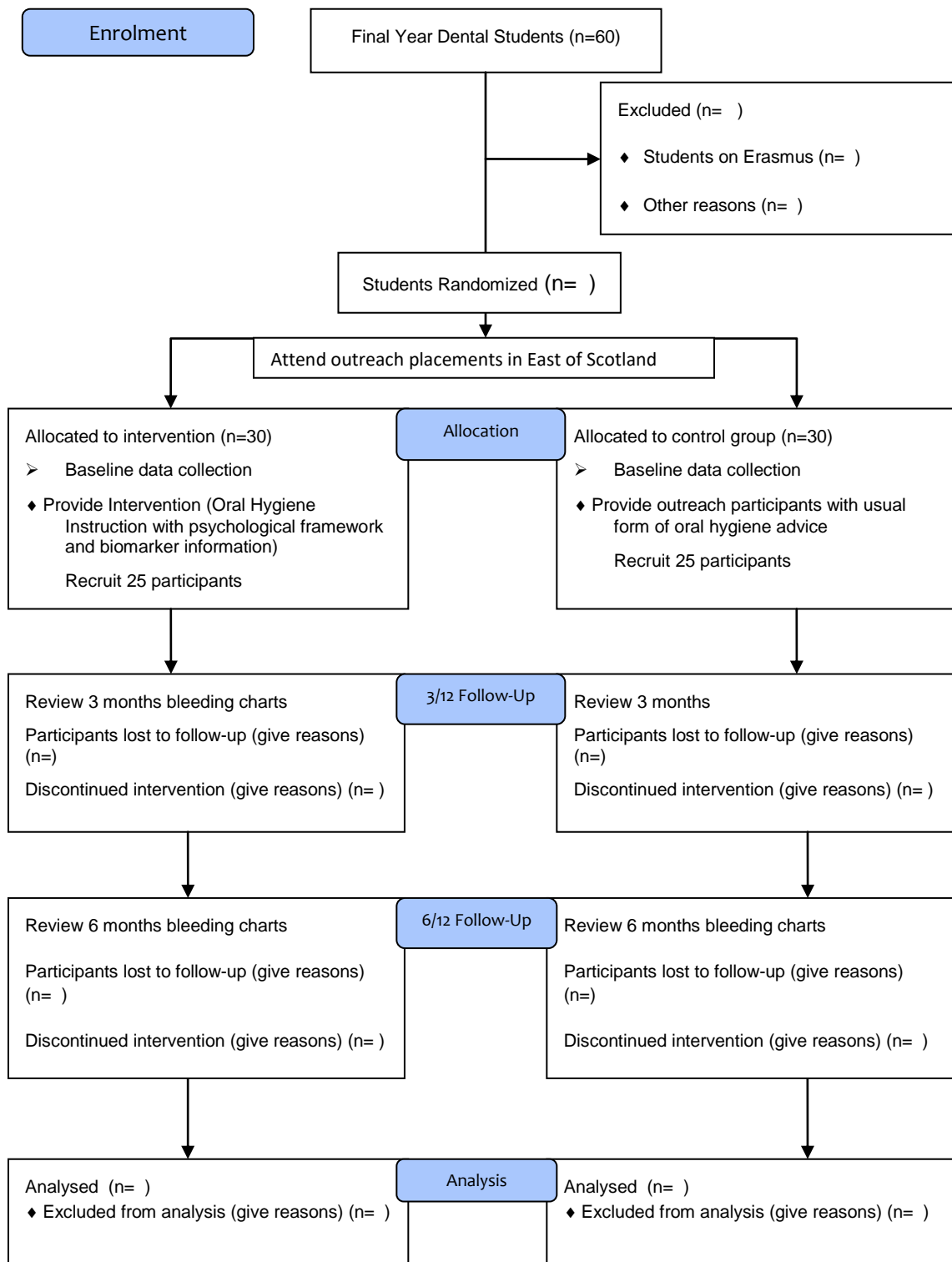
As part of the final year course in healthcare law and professionalism, students will receive lectures on professionalism and evidence based dentistry. They will be provided with a day's training on consenting patients for clinical trials, and ethics issues involved in running a clinical trial as part of good clinical practice.

All final year dental students will participate in the clinical trial, (which will be an integral part of the course). The students and supervisors will be trained in the trial methodology and the students randomised to either intervention or control groups. The intervention group will receive separate training on implementing the psychological framework and the use of biomarkers in the planning phase of the intervention. They will also have access to trial methodology and paperwork through the university website to use as a reference throughout the trial. The control group will have access to the trial method but not have knowledge of the intervention.

Dental students will, under direct supervision, record the plaque and bleeding measurements and will be responsible for the delivery of the intervention and control. Consent of the patients will be carried out jointly with the clinic supervisors (who will have received training on the study design and protocol, including GCP and consenting patients for trials).

Patients will be recruited over a six month period, until each practitioner involved has recruited 25 patients. Patients will be reviewed at three and at six months by a different student practitioner who will be blind as to whether the patient was allocated to the intervention or the control group. Patients themselves will be unaware of their group allocation.

Outreach Trial Flow Diagram



4. STUDY POPULATION

4.1 NUMBER OF PARTICIPANTS

All 60 final year dental students will each recruit patients while at dental outreach attachments. The six clinics involved are spread over four health boards. Each student practitioner will recruit 25 patients, over a six month period, to give an overall sample size of 1500.

All patients recruited to the trial will be adults who are attending for routine care.

4.2 INCLUSION CRITERIA

- Adult patient (16 years old or over, no upper age limit)
- Dentate, or partially dentate
- Generally good health

4.3 EXCLUSION CRITERIA

- Medical history contraindicates periodontal examination (e.g. known bleeding disorder)
- Completely healthy gums with no plaque
- Patients without any natural teeth
- Pregnancy
- Patients under 16 years

5. PARTICIPANT SELECTION AND ENROLMENT

5.1 IDENTIFYING PARTICIPANTS

Patients will be identified in advance from the appointment book, with the R4 Kodak software used by the outreach clinics. Patients attending for routine treatment will be sent information about the study and an invitation to participate along with their appointment letter. Patients who do not receive a pack by post may be given one when they book a further appointment and would be able to be assessed for eligibility the following appointment.

5.2 CONSENTING PARTICIPANTS

Patients who wish to take part in the study will be consented by clinic staff in conjunction with the dental student responsible for delivering their care at that appointment. Consent forms will be signed by all three parties to identify that the process has taken place.

5.3 SCREENING FOR ELIGIBILITY

Patients will be screened by the student before consent procedures. The dental student will ensure that the patient does not meet any criteria for exclusion:

- Patients without natural teeth
- Medical history contraindicates probing of the gingivae (e.g. known bleeding disorder)
- Patients aged 16 and under
- Pregnancy
- Patient with no gingival bleeding, and no plaque.
-

This will involve the student checking the medical history and dental chart for existing patients; this is routine procedure at the clinics. For all new patients, the student will take a medical history and perform basic periodontal examination, and dental chart which are standard procedures.

5.4 INELIGIBLE AND NON-RECRUITED PATIENTS

Patients meeting exclusion criteria will be thanked for their interest. Any patients not wishing to participate in the trial will receive their treatment as usual at the clinic, which may or may not include oral hygiene instruction.

5.5 RANDOMISATION

5.5.1 Randomisation

Students will be randomly allocated to control and intervention groups by means of block allocation of their matriculation numbers. Patients in outreach clinics are currently booked to the clinic chair, not specifically named operators. Therefore the patients are not specifically booked to a student; this will ensure the patient group allocation is in no way predetermined.

5.5.2 Treatment Allocation

Participants will receive the intervention or the control as per the treating dental student's group allocation.

5.5.3 Emergency Unblinding Procedures

Tayside Academic Health Sciences Centre, who this study is being carried out in collaboration with will hold the coding for the operators and participants, it will therefore be possible, should the need arise for a member of the research team to unblind the group allocation for a particular patient.

However for this study, as there are minimal foreseeable risks of the intervention, it is unlikely such a situation would occur.

5.5.4 Withdrawal procedures

If a participant becomes pregnant during the trial or for any reason wishes to withdraw from the study, they may do so by informing the trial team of their intention. Alternatively if they choose to inform outreach clinic, then the principal investigator for the clinic will in turn advise the trial team.

Participants who withdraw may still wish to complete questionnaires. If a patient withdraws due to geographical reasons or because they are receiving treatment elsewhere, it is feasible to send the review questionnaire to that patient to measure their oral hygiene knowledge and behaviour.

Participants who withdraw from the study will still receive treatment as usual at the outreach clinic as they wish.

If the level of withdrawn participants is high it may be necessary to extend the recruitment period, although recruitment would have to remain within that academic year (the same group of students).

For participants who withdraw and do not wish to receive study questionnaires, then no further contact will be made by the study team.

The study team can not foresee any incidences where a participant would be withdrawn for safety reasons as this is considered to be a low risk intervention.

6. INTERVENTION AND CONTROL INFORMATION

6.1 Intervention group

The intervention group will be trained to provide oral hygiene instruction within a simple psychological frame, enhanced with biomarkers. This follows the Tell-Show-Do-Plan framework (Appendix 1) implemented by Clarkson. The addition of biomarker of bleeding into the intervention will strengthen the intervention so that participants have a plan of what to do if they become aware of the presence of gum disease: brush more carefully and regularly. The student will use visual aids and the instruction will be in the patient's own mouth. They will follow the instructions (outlined in Appendix 1), informing the patient of their charts, showing them where and how to clean, getting the patient to do it for themselves and helping the patient to plan when to clean.

6.2 Control group

The control group will provide oral hygiene instruction or advice as they usually would on the clinics, without the use of any prompt sheets. Observational studies in outreach clinics indicate students rarely to discuss the plaque or bleeding charts specifically. Procedures are outlined as in Appendix 1.

7. TRAINING OF STUDENTS AND STAFF

7.1 Student training and Support

Final year dental students currently receive no training in clinical research skills. In order to enhance the current undergraduate course and dental undergraduate understanding of clinical research importance and its place in primary care dental practice the final year dental students will receive training during the first week of their final year. This is a week of lectures with no clinical attachments.

During these lectures the students will learn about the importance of primary care dental research and its relevance to patient care as well as its part in continuing professional development. Students will be required to participate in clinical research while on dental outreach attachments. Students will receive training in the methodology of this specific trial and reasons behind this study design. They will, in the form of a video receive training in measuring and recording plaque and gingival bleeding, and those allocated to the intervention group will be trained in the method for delivery of the intervention. Participation in clinical research will form an integral part of the final year course.

All materials relating to the trial will be posted on the Dundee University website; only those in the intervention group will be given specific access to the intervention methodology, this will be achieved with the help of the dental IT department.

Students will have training in consenting patients for clinical trials and complete good clinical practice training in relation to research. GCP, consenting patients for trials or specifics of methodology may be subject to examination as part of final year assessment.

7.2 Outreach Staff Training and Support

The sponsor of this trial is Dundee University, with whom outreach staffs currently hold honorary contracts. The staffs involved during the trial will receive training in GCP and in consenting patients for clinical trials in the same manner as the dental students; they will be conversant in the level of knowledge expected of the undergraduates. Staff will be trained in the trial methodology and paperwork and receive packs containing information of contacts and trial methodology to take away. They will also have access through the Dundee website, to the same videos the students can access. Outreach staff will not initially be made aware of the intervention; this decision has been made in order to maintain patient blinding of allocation and recording of outcome measures at reviews.

8. STUDY ASSESSMENTS

8.1 Safety Issues

No safety issues have been identified for this proposed intervention.

8.2 Measurements

8.2.1 Plaque Measurement

Dental plaque will be measured according to the plaque scoring methods the dental students currently use. This is a four surface dichotomous scoring system (O'Leary, Drake et al. 1972). Each tooth is divided into buccal, lingual/palatal, mesial and distal surfaces. A periodontal probe is run around the gingival margin of the tooth and each surface scored as either plaque or no plaque. The mesial and distal surfaces are measured by running a probe as far as possible into the contact point from either side.

8.2.2 Bleeding Measurement

Bleeding will be measured as bleeding on probing at the gingival margin. A periodontal probe is run around the gingival margin of the tooth and surfaces recorded as bleeding or not bleeding. Delayed bleeding is counted as bleeding. This is then recorded on the O'Leary four point plaque scoring system.

8.2.3 Acceptability of Clinical Research in Outreach

The overall acceptability of clinical research in the dental outreach clinics will be assessed in relation to the time spent delivering the trial and the overall attitudes of the staff, students and patients together with the perceptions measured in the participant, student and supervisor questionnaires.

8.2.4 Time

It is intended that this clinical trial will fit into the standard outreach appointment time of 90min. At present this appointment time is reported as being underutilised apart from in the small number of instances where advanced treatment is being undertaken. We would expect that the undergraduates, with the high level of support they receive in outreach, to be able to complete most procedures in 60mins. In order to allow for a ten minute period to write up notes and change over the units, the appointment times have been kept as 90mins in the majority of outreach clinics. This clinical trial is expected to fit conveniently into this 20-30min period. This will include time for communicating the trial information, consenting the patients(5min), measuring and recording (5-10min), delivering the intervention (5min) and finally questionnaires and writing up notes (5min), allowing 5min for changing over unit for the next patient.

The trial will record the time taken to follow the protocol and also whether participants were still able to receive treatment at the same appointment. If they are not able to receive usual treatment, the students are to record reasons behind this.

8.2.5 Patient Outcomes

Patients will complete a pre-trial and review visit questionnaires. Previously validated questions will measure the patient outcomes which are based on the Theory of Planned Behaviour and Social Cognitive Theory for predicting oral hygiene behaviour. These are:

- i. Intention towards cleaning
- ii. Self-efficacy expectancies towards tooth cleaning

- iii. Perceived behavioural control towards tooth cleaning
- iv. Outcome expectancies towards tooth cleaning
- v. Attitudes towards tooth cleaning
- vi. Subjective norms towards tooth cleaning
- vii. Self reported brushing time
- viii. Self reported brushing frequency
- ix. Self reported rinsing behaviour

8.2.6 Perceptions of and Attitudes to Clinical Research in Outreach

Questionnaires will also investigate attitudes to clinical research in dental outreach for the patients:

- i. Willingness to undertake research in the future
- ii. Perceptions of clinical research in outreach.
- iii. Patients not wishing to take part will be given the opportunity to complete a questionnaire exploring reasons behind this to hopefully facilitate the design of future studies in outreach.

8.2.7 Self reported Behaviours of dental students during the Clinical Trial

- i. Following the protocol
- ii. Perceived accuracy of measurements
- iii. Perceived delivery of intervention
- iv. Ability to complete dental treatment at the trial appointment
- v. Timekeeping

8.2.8 Intention to Participate in Future Clinical Research

Intentions of the three groups involved to participate in future research in primary care.

9. DATA COLLECTION

Patients enrolled in the study will all be dental outreach patients. They therefore will have dental notes in the clinic Kodak R4 system. This will act as source data for the Case Report Forms. Additional data which will be collected for the purposes of the study will include:

- Plaque charts (dichotomous O'Leary charting)
- Bleeding charts (dichotomous O'Leary charting)
- Questionnaires.

The charts for the purposes of the study will be on paper, the charts and patient questionnaires will be coded.

At subsequent 3 month and six month review visits the plaque and bleeding measurements will be repeated, charted and again added to the CRF together with the patient questionnaire for that visit.

The charts and questionnaire will all be marked with the patient's unique study ID number which will be linked to the enrolment log for the trial.

All data will be collected from the clinics at least monthly by the research team and transferred to the Health Informatics Centre for storage, data entry and ultimately analysis.

Participants who do not attend for a review visit will be contacted by the clinic and offered another appointment. If they subsequently fail to attend then the questionnaire will be mailed out with a prepaid envelope and a note sent to the trials team from the clinic to explain the patient has been lost to follow-up.

10. STATISTICS AND DATA ANALYSIS

10.1 SAMPLE SIZE CALCULATION

Lack of bleeding on gingival probing is the measure of health. Bleeding from the gum margin in the general population is on average, 40% of sites. An improvement in terms of reduction by 10% of sites to be bleeding is required to be clinically significant.

To give 80% power at 5% significance level, and assuming an intra-cluster correlation coefficient of 0.05.

In order to allow for clustering (where the cluster i.e. the student is randomised) the IF = $1 + (m - 1) * ICC = 1 + (15 - 1) * 0.05 = 1.7$

So for a cluster trial we require $1.7 * 376 = 639$ in each group or 1278 in total. To allow for approximately 20% drop out rate then total number of Outreach patients to be recruited = 1500.

It is estimated that this will take at least 3-4 months for the students to recruit 25 patients each, we plan to allow recruitment over a 6 month period to compensate for the failed to attend rate of patients in the outreach clinics.

10.2 PROPOSED ANALYSES

Data collected will be assessed for normality. Then parametric or non parametric statistical tests will be employed as appropriate to assess whether there have been any statistically significant differences CI 80%.

The proposed analyses will investigate comparisons between the intervention group receiving the enhanced oral hygiene instruction and the control group of basic oral hygiene. Specifically, looking for clinically significant improvement in oral hygiene and bleeding from baseline at both three and six months for each group:

- Plaque scores
- Bleeding scores (measure of gum health)

Psychological measures from the questionnaires:

- Intention to clean teeth
- Plans for cleaning of teeth
- Subjective norms and self efficacy
- Attitudes to oral hygiene
- Perceived behavioural control

Patient questionnaires will investigate the attitudes of the outreach patients to participating in clinical research during their appointments and also their intentions to participate in future research trials.

For the dental students involved in the delivery of the intervention, questionnaires will self reported behaviour during the trial. Both the intervention and control group will be compared to

each other for differences, and compared to their baseline scores for any statistically significant shift in attitudes and intentions towards clinical research in dental outreach setting

Qualitative information will be coded and grouped as appropriate, analysis looking for trends in group perceptions.

11. ADVERSE EVENTS

No adverse events are expected for this one off intervention; however the University of Dundee SOP on AE recording will be adhered to in this study.

11.1 DETECTING AEs AND SAEs

As the intervention is oral hygiene instruction it is highly unlikely there would be any AEs or SAEs resulting from this study. Any participants reporting AEs would discuss this with clinic staff or may contact the trial team directly.

All AEs and SAEs will be recorded from the time a participant consents to join the study until the last study visit.

The Investigator will ask about the occurrence of AEs/SAEs at every visit during the study. Open-ended and non-leading verbal questioning of the participant will be used to enquire about AE/SAE occurrence. Patients will also be asked if they have been admitted to hospital, had any accidents, used any new medicines or changed concomitant medication regimens. If there is any doubt as to whether a clinical observation is an AE, the event will be recorded.

11.2 RECORDING AEs AND SAEs

The investigators do not see any reason to believe that the proposed intervention will result in SAEs or SuSARS. We do not expect to report hospital admissions, changes in concomitant medications nor other health problems as AEs or SAEs unless there is direct evidence that the AE has been caused by overly forceful brushing of the teeth. However, should they occur they will be recorded in keeping with normal practice.

12. PREGNANCY

As the gingival measure of bleeding can be affected by hormones during pregnancy, this trial will exclude any patients who are pregnant. Participants who become pregnant during the trial will be withdrawn from follow up measures.

13. TRIAL MANAGEMENT AND OVERSIGHT ARRANGEMENTS

13.1 PROJECT MANAGEMENT GROUP

The trial will be coordinated by a Project Management Group, consisting of the Chief Investigator and Principal Investigator in Dundee, A Trial Manager and principal investigators at each site.

13.2 TRIAL MANAGEMENT

The Principal Investigator, Dr Kerry Richardson, will act as the Trial Manager. She will oversee the study and will be accountable to the Chief Investigator. The Trial Manager will be responsible for checking the CRFs for completeness, plausibility and consistency. Any queries will be resolved by contacting the site Principal Investigators or delegated member of the trial team.

A Delegation Log will be prepared for each site, detailing the responsibilities of each member of staff working on the trial.

13.3 CENTRAL TRIAL OFFICE

The Central Trial Office, Tayside Clinical Trials Unit (TCTU), will provide support to each site. The office will be responsible for randomisation, collection of data in collaboration with the Trial Manager (Kerry Richardson), data processing and analysis. Publication and dissemination of the study results will be coordinated by Kerry Richardson in collaboration with the Chief Investigator, Investigators, TCTU and the Scottish Dental Practice Based Research Network, who have had an advisory role in this trial.

13.4 TRIAL STEERING COMMITTEE

A Trial Steering Committee (TSC) will be established to oversee the conduct and progress of the trial. The terms of reference of the Trial Steering Committee, the draft template for reporting and the names and contact details are detailed in Appendix 2

13.5 DATA MONITORING COMMITTEE

An independent Data Monitoring Committee (DMC) will not be necessary for this trial as there is regular supervision of the Principal Investigator/ Trial Manager through her PhD supervision, the intervention is a 'one off' intervention, and there is regular contact (monthly) with all study sites. The study is low risk and part of a PhD programme for the PI.

13.6 INSPECTION OF RECORDS

Principal Investigators and institutions involved in the study will permit trial related monitoring, audits, REC review, and regulatory inspection(s). In the event of an audit, the Investigator agrees to allow the Sponsor, representatives of the Sponsor or regulatory authorities direct access to all study records and source documentation.

13.7 STUDY MONITORING

A monitor, designated by the Sponsor, or an appointed local monitor will visit the Dundee study site prior to the start of the study and during the course of the study. All other study sites will receive study induction training and regular monitoring of study progress at least monthly throughout the study by the sponsors representative.

A copy of the monitoring plan is given in Appendix 4.

13.8 RISK ASSESSMENT

An independent risk assessment carried out by the designated monitor is given in Appendix 5.

13.8.1 Potential Risks

There are minimal potential risks from this study. It may be possible for some patients to begin overzealously cleaning their teeth. As subjects are undergoing routine care in dental outreach this would be recognised early and appropriate advice given.

13.8.2 Minimising Risk

The possibility of overzealous cleaning and subsequently damaging tooth or gum structure will be minimised by the regular review process built into the study design.

14. GOOD CLINICAL PRACTICE

14.1 ETHICAL CONDUCT OF THE STUDY

The study will be conducted in accordance with the principles of good clinical practice (GCP).

Approval will be obtained from the appropriate REC and local NHS R&D approval will be obtained prior to commencement of the study.

14.2 INVESTIGATOR RESPONSIBILITIES

The Chief Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff which in this case is a Senior Dental Officer who has been nominated PI for each outreach centre. Delegated tasks must be documented on a Delegation Log and signed by all those named on the list.

14.2.1 Informed Consent

The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the

participant should be performed by the Investigator or designated person, and must cover all the elements specified in the Participant Information Sheet/Informed Consent.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant should be informed and agree to their dental records being inspected by regulatory authorities but understand that their name will not be disclosed outside the clinic.

The Investigator or delegated member of the trial team and the participant should sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant should then receive a copy of this document and a copy should be filed in the Investigator Site File (ISF).

14.2.2 Study Site Staff

The Chief Investigator must be familiar with the protocol and the study requirements. It is the Investigator's responsibility to ensure that all staffs assisting with the study including Principal Investigators for each site and dental students are adequately informed about the protocol and their trial related duties.

14.2.3 Data Recording

The Investigator is responsible for the quality of the data recorded in the CRF.

14.2.4 Investigator Documentation

Prior to beginning the study, each Investigator will be asked to provide particular essential documents to the Sponsor, including but not limited to:

- An original signed Investigator's Declaration (as part of the Clinical Trial Agreement documents);
- Curriculum vitae (CV), signed and dated by the Investigator indicating that it is accurate and current.

The Chief Investigator, with the agreement of the Sponsor, will ensure all other documents required for compliance with the principles of GCP are retained in a Trial Master File and that appropriate documentation is available in local ISFs.

14.2.5 GCP Training

All study staff must hold evidence of appropriate GCP training or undergo GCP training.

14.2.6 Confidentiality

All evaluation forms, reports, and other records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor, its designee, Regulatory Authorities, or the REC. The Investigator and study site staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee would be obtained for the disclosure of any said confidential information to other parties.

14.2.7 Data Protection

All Investigators and study site staff involved with this study will comply with the requirements of the Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Access to collated participant data will be restricted to those clinicians treating the participants.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

15. STUDY CONDUCT RESPONSIBILITIES

15.1 PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant, will be reviewed and approved by the Chief Investigator. Amendments to the protocol will be submitted in writing to the appropriate REC and local R&D for approval prior to participants being enrolled into an amended protocol.

15.2 PROTOCOL VIOLATIONS AND DEVIATIONS

The Investigator will not implement any deviation from the protocol without agreement from the Chief Investigator and appropriate REC and R&D approval except where necessary to eliminate an immediate hazard to trial participants.

In the event that an Investigator needed to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF. If this necessitates a subsequent protocol amendment, this will be submitted to the REC and local R&D for review and approval if appropriate.

15.3 STUDY RECORD RETENTION

All study documentation will be kept for at least 5 years.

15.4 END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators and/or the trial steering committee have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants and ensure that the appropriate follow up is arranged for all involved.

A summary report of the study will be provided to the REC within 1 year of the end of the study.

15.5 CONTINUATION OF INTERVENTION FOLLOWING THE END OF STUDY

Participants will be free to continue implementing the intervention following the end of the study if they wish to do so. As the intervention is oral hygiene, it would be hoped that all participants would continue this behavior at the end of the trial.

16. REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

16.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team. On completion of the study, the study data will be analysed, tabulated and a clinical study report will be prepared.

16.2 PUBLICATION

The results of the trial will be presented at the annual dental outreach meeting for Dundee University. There will also be the opportunity to present at national and international level. It would be hoped that the results will be published in peer reviewed journals and go on to inform teaching in the outreach clinics affiliated with Dundee University.

Summaries of the results will be sent to the dental students involved through their vocational trainee schemes.

Summaries of results will also be made available to Investigators for dissemination within their clinics (where appropriate and according to their discretion).

16.3 PEER REVIEW

This study is being conducted as part of a PhD programme and has been reviewed by University of Dundee Academic supervisors. In addition it has been adopted by the TCTU as an approved study and has been subject to TCTU review, Research Governance review and ongoing support from TAHSC in its development and oversight.

17. REFERENCES

- Chapple, I. L. C. (2009). "Periodontal diagnosis and treatment - Where does the future lie?" Periodontology 2000 **51**(1): 9-24.
- Clarkson, J. E., L. Young, et al. (2009). "How to influence patient oral hygiene behavior effectively." Journal of Dental Research **88**(10): 933-937.
- O'Leary, T. J., R. B. Drake, et al. (1972). "The plaque control record." Journal of Periodontology **43**(1): 38.
- Renz, A., M. Ide, et al. (2007). Psychological interventions to improve adherence to oral hygiene instructions in adults with periodontal diseases. Cochrane database of systematic reviews (Online).
- Soldani, F. A., L. Young, et al. (2008). "One-to-one oral hygiene advice provided in a dental setting for oral health." Cochrane Database of Systematic Reviews(4).
- Walsh, M. M., B. H. Heckman, et al. (1985). "Use of gingival bleeding for reinforcement of oral home care behavior." Community Dentistry and Oral Epidemiology **13**(3): 133-135.

APPENDIX 1: DENTAL OUTREACH ORAL HYGIENE STUDY

INTERVENTION GUIDANCE

Intervention Guidance

Simple Spoken Advice

Current best evidence suggests that simple chair-side advice is effective in improving oral hygiene when framed using a psychological framework (Tell-Show-Do-Plan). The integration of biomarker will improve patient adherence to advice given.

- Discuss the five key oral hygiene messages:
 - ❖ Brush teeth **twice** daily – once last thing at night and on one other occasion

- ❖ Use **fluoride** toothpaste
- ❖ Brush for **two** minutes, use the **timer**!
- ❖ Bleeding gums require **more careful** cleaning
- ❖ **Spit** but do not rinse

Instructing your patients:

- Sit the patient **upright**, **remove** your **mask** and the patient's safety **glasses**, if the patient usually requires glasses get them to put them on.
- **Tell** the patient that you have discovered bleeding and/or plaque, and that bleeding is a sign of gum disease, that plaque causes tooth decay and gum problems.
- **Show** them in their mouth, using the hand mirror, areas where this is a problem (bleeding/plaque as per charts).
- **Show** them how to **correctly clean** these areas. (DO NOT TELL THEM ABOUT 'BASS' TECHNIQUE OR 45° ANGLES!), the focus is on them **feeling** and **seeing** the correct method.
- **Do** get them to **demonstrate** they can clean effectively in these areas.
- **Do** get them to feel how **smooth** their clean teeth are.
- **Do** ensure they understand **bleeding** means they need to brush **more carefully** in these areas.
- **Plan** that they will clean at two specific times of day
- **Plan** they will **look for bleeding** and clean these areas **more carefully**.
- Ask if there are any questions.

Notes:

- Always be encouraging and positive, even if their toothbrushing technique is poor.
- If their technique is correct tell patients they are brushing in 'exactly the right way' and that you are confident they can 'keep on brushing as well as they did in the surgery' (*use your own words*).
- If their technique could be improved, please tell patients that they have 'done well' but that you have 'some suggestions for how they could do even better' (*again use*

*your own words, the important point is that you are always positive and encouraging and **never negative** or **discouraging**).*

- Ask patients whose technique needed improvement to demonstrate using their toothbrush again.
- Once you are satisfied with the patients' technique, tell patients they are brushing in exactly the right way and that you are confident they can 'keep on brushing as well as they did in the surgery' (*use your own words*).
- Encourage patients to make a **plan** for when they will brush their teeth before they leave the surgery. The best way is to match toothbrushing to something they already do every day e.g. before going to bed, after breakfast etc. Use the leaflet as a prompt.

STUDENT GUIDANCE

Student Protocol

Recruitment of Patients

- The Outreach clinic will have identified patients who are to attend for routine appointments.
- These patients should have received the study pack containing the '*Patient Invitation Letter*' and '*Patient Information Sheet*'. The pack **must** have been received at least **24 hours** before the appointment. Please check your patient has received the pack 24 hours in advance of today's appointment.
- If you have an emergency patient, it is acceptable for them to take away information about the trial, and be assessed for eligibility at the following visit. It is NOT appropriate for patients attending for emergency care to be recruited at the emergency visit. Equally, if a 'routine care' patient attends with an acute problem,

the acute condition **must** take priority over and above the trial. The patient may of course, be re-appointed for the trial visit as appropriate.

First Trial Visit (baseline)

Assessing Willingness and Eligibility

- After introducing yourself to the patient, find out whether they have read the study information. If they have, discuss whether they are interested in participating. (If they did not receive the information you can still discuss the study and give a pack to them but they will not be eligible to participate in the trial until their next outreach appointment.)
- If they **do not** wish to participate, record refusal on the '*screening log*'. Record the **reason for refusal** if one is given. (Patients **do not** have to give a reason.)
- If **yes**, assess eligibility to take part. (See 'patient eligibility checklist').
- If the potential participant is **not eligible** to take part please record on the *screening log*. Give the patient the opportunity to ask questions. To maintain confidentiality the reason for **ineligibility** should **not** be recorded.
- If your patient is NOT interested in participating in the trial please ensure the R4 study icon is activated accordingly to prevent the patient being asked to participate at subsequent appointments.
- Patients who are eligible and wish to participate may then receive a full explanation of the trial and go through consenting process.

Obtaining Signed Consent

- After the consent process, willing patients should complete the '*Patient Consent Form*'.
- Please ensure the participant's address is entered on the consent form, and that the form is initialled correctly.
- **Please ensure the R4 study participant icon is activated in the notes.**

Record the time taken to assess eligibility and go through the consent process on the '*Baseline Visit Economic Evaluation*' form. *The consent process is complete when the*

patient is satisfied as is the supervising dentist the forms should be completed as a record that the consent process has been carried out.

Baseline Data

Patient Questionnaire

- Before you start recording plaque please ensure the patient has completed the baseline questionnaire, if not ensure they complete this before you proceed. *It is anticipated that questionnaires will take approximately 3 – 4 minutes to complete.* Place the questionnaire in the plastic pocket provided in your trial folder.

Clinical Examination

- Carry out the plaque and gingival bleeding examination and record the results on the '*Baseline Clinical Measures Form*'. Guidance in the procedure to be followed is given on the '*Plaque and Gingival Bleeding Indices*' and the '*Plaque and Gingival Bleeding Scoring Criteria Guidance*' sheets.

Record the time taken to complete and record the plaque and gingival bleeding examination on the '*Baseline Visit Economic Evaluation*' form.

Control

- After the plaque and bleeding charts please proceed to the oral hygiene instruction
- You will then give OHI as per your group allocation. Under NO circumstances disclose to the patient your group allocation.
- After delivering OHI you may check with staff whether you are to carry out any further treatment for the patient at this appointment, please record on the '*Baseline Visit Economic Evaluation*' form whether you carry on with routine care during this appointment, if you do not record the reason why.
- At the end of the visit, thank your patient and ensure **they have a review appointment** made for three months* time as well as any other appointments for usual treatment.

- Place the '*Baseline Clinical Measures Form*' in the envelope provided and seal this. **Please ensure all paperwork to be given to the research team has your trial ID code and the patients trial ID, this includes questionnaires, consent forms, charts etc.**

Record the time taken to give the oral hygiene advice and instruction on the '*Baseline Visit Economic Evaluation*' form.

Baseline Data which has been collected

- It is important that you carefully fill out all the trial forms and clearly mark the identifying codes in the appropriate spaces.
- All data collected should be carefully sealed in the envelope provided and placed in the trial box in the outreach clinic.
- Please do NOT remove any of the trial data from the clinic, it will be collected by the researcher

Follow-Up Visit 1

Clinical Examination

- The review appointment should be in approximately 3 months* time (\pm 2 weeks) following today's appointment. If the patient requires routine treatment (e.g. is nearing the end of a lengthy treatment plan), then routine treatment may also take place at this appointment.
- Carry out a follow-up plaque and gingival bleeding examination and record the results on the '*Follow-Up Clinical Measures Form*'.
- Place the '*Follow-Up Clinical Measures Form*' in the envelope provided and put in the plastic pocket provided in your trial folder.

Record the time taken to complete and record the plaque and gingival bleeding examination on the '*Follow-Up Visit Economic Evaluation*' form.

Data which has been collected

- Data collected from your patients should be placed in the trial envelope and sealed and put in the trial box in the outreach clinic for collection by the researcher

APPENDIX 2: TRIAL STEERING COMMITTEE

Chief Investigator: Dr A.F. Hall (University of Dundee)

Principal Investigator: Dr K.N. Richardson (University of Dundee)

Principal Investigator: Prof. J.E. Clarkson (University of Dundee)

Principal Investigator: Dr L. Young (Scottish Dental Practice Based Research Network)

Representative from Tayside Academic Health Sciences Centre

APPENDIX 3: DATA MONITORING COMMITTEE

Tayside Academic Health Sciences Centre

Chief Investigator: Dr A.F. Hall (University of Dundee)

Principal Investigator: Dr K.N. Richardson (University of Dundee)

Principal Investigator: Prof. J.E. Clarkson (University of Dundee)

Principal Investigator: Dr L. Young (Scottish Dental Practice Based Research Network)

APPENDIX 4: MONITORING PLAN, QUALITY CONTROL AND QUALITY ASSURANCE

We are using an adapted monitoring plan based on SOP39 from TAHSC portfolio.

MONITORING PLAN

Study Title: Dental Outreach Oral Hygiene Study

R&D Project ID:

Investigator: Dr A Hall

1. Trial oversight committees:

	Y	N	N/A
Trial management group			
Data monitoring committee			
Trial Steering committee			
Other/comments:			

2. Central monitoring:

	Y	N	N/A
Data collected and validated via central coordinating centre ('good housekeeping')			
Trial data recorded on database with inbuilt data checks (eg value ranges etc)			
Randomisation done via central coordinating centre (verify eligibility)			
Investigator training/Investigator meetings			
Other/comments:			

3. On-site monitoring:

	Y	N	N/A
--	---	---	-----

Investigator Site File			
SDV informed consent			
SDV of critical data (eg endpoint data)			
SDV of safety data (AEs, SAE, SUSARs) and timeliness of reporting			
SDV patient eligibility			
Storage and security of trial data			
Other/comments:			

4. Expected frequency of on-site monitoring:

This study is considered low risk by the university of Dundee sponsorship committee, however to ensure the study is run to GCP standards all sites will be regularly monitored by the PI Kerry Richardson every 4-6 weeks. The purpose of the monitoring visits are to provide support for the students, to identify any problems with the students, recruitment, consent and data validity

Completed by: (Designated Monitor)

Signature:

Date:

APPENDIX 5: RISK ASSESSMENT

As per University of Dundee sponsorship risk assessment.

Appendix 6

Ethics Committee Confirmation Letter from Fife and Forth Valley



Fife



Forth Valley



Tayside

East of Scotland Research Ethics Service

Fife & Forth Valley Research Ethics Committee
Research Ethics Office
TAHSC, Residency Block C
Ninewells Hospital & Medical School
DUNDEE
DD1 9SY

Dr Andrew F Hall
Senior Lecturer/ Honorary Consultant in
Restorative Dentistry
University of Dundee Dental School
Frankland Building,
Smalls Wynd
DUNDEE DD1 4HN

Date: 10 August 2010
Your Ref:
Our Ref: FB/10/S0501/43
Enquiries to: Miss Fiona Bain
Extension: Ninewells extension 32701
Direct Line: 01382 632701
Email: fionabain@nhs.net

Dear Dr Hall

Study Title: Improving Oral Hygiene in Patients Attending Primary Care Dental Outreach Facilities: Through Delivery of Enhanced Oral Hygiene Instruction, Framed using Psychological Theory
REC reference number: 10/S0501/43
Protocol number: n/a

The Research Ethics Committee reviewed the above application at the meeting held on 03 August 2010. Thank you for attending with Dr Richardson to discuss the study.

Ethical opinion

The following points are for information only and there is no requirement to respond unless there are any inaccuracies:

1. In response to a question about whether the patients could refuse to be seen by a student, it was indicated that patients sign a consent form to agree to be seen and treated by a student at the Outreach clinic. If they do not sign this, they would be seen in a Primary Care Clinic.
2. It was explained that the psychological framework came from 'come show do'.
3. Dr Hall explained that part of the final year has an element of professionalism and the proposal is that students should take part because it is part of the course. They would be encouraged as much as possible, but it was not possible to fail them if they did not want to take part.
4. With regard to the questionnaire for those who did not wish take part, Dr Richardson said they felt that these patients were important as well because they may be interested in future trials. It was not compulsory to complete the questionnaire.
5. In answer to a question about whether the students were participants or collaborators, Dr Hall said that they are participants, but undertaking the research on patients. There were six or seven outreach clinics with a huge amount of work being undertaken. Students were learning the full gamut of dentistry with an increasing emphasis on the quality of care that they provide. There was



1. The Participant Information Sheet should be amended as follows:

- It should state up front that this is for an educational qualification as follows: 'My name is Dr Kerry Richardson and I am a PhD Student at the University of Dundee. I am required to undertake a project as part of my course and invite you to take part in the following study. However, before you decide to do so, I need to be sure that you understand firstly why I am doing it, and secondly what it would involve if you agreed. I am therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including your friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later.'
- It should include a statement about using anonymised quotes and specific consent obtained within the Consent Form.
- Under the heading 'Is there a payment for taking part in the study?' it should be made clear that travel expenses may be available from the relevant Health Board if they currently receive these for dental appointments.
- Please use the standard wording on review and monitoring as follows: 'The Fife & Forth Valley Research Ethics Committee, which has responsibility for scrutinising proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the university of Dundee and <<insert name of NHS Health Board>>, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.'
- It should include a complaints paragraph along as follows: 'If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the University of Dundee, who are acting as the research sponsor. Details about this are available from the Dundee Dental School, University of Dundee, Park place, Dundee, Scotland, DD1 4HN. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the << name of Complaints Office, address & telephone number>>. Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against <<name of NHS board>> but you may have to pay your legal costs.'
- It should include a telephone number, since not everyone will have access to the internet.
- Please include the following at the end: 'Thank you for taking the time to read this Information Sheet and for considering taking part in this study'

Please submit a revised version of the Participant Information Sheet, which should include a new version number and new full date.

2. The Information Leaflet should be amended as follows:

- In the paragraph that begins with 'We would like to invite you ...' the word 'best' should read 'better'.
- It should include a telephone number, since not everyone will have access to the internet.



Please submit a revised Information leaflet, which should include a new version number and new full date.

3. The Consent Form requires to be amended as follows:

- It should include the PIS version number and date in the first statement.
- As previously mentioned, it should include a statement about the use of anonymised quotes along the following lines: 'I understand that quotes made by me may be used in any written report, but these will be anonymised. I agree to the use of these quotes.'

Please submit a revised Consent Form, which should include a new version number and new full date.

4. The Questionnaires should be amended as follows:

- The greeting in the Patient Questionnaires should be amended to read 'Dear Clinic Patient'.
- In the Patient Review Questionnaire, it is suggested that you include a question about smoking.

Please submit revised version of these Questionnaires, which should include a new version number and new full date.

5. Please submit a copy of the 'Thank you' letter that is intended to be sent out to participants for our records.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Investigator CV		
Protocol	1	19 July 2010
CV - Dr Kerry Richards		16 July 2010
Eligibility Checklist		
REC application		20 July 2010
Covering Letter		19 July 2010
Summary/Synopsis	1	19 July 2010
Letter from Sponsor		21 July 2010
Questionnaire: Outreach Patient Baseline	1	19 July 2010
Letter of invitation to participant	1	19 July 2010
Participant Information Sheet	1	19 July 2010



Document	Version	Date
Participant Information Sheet: Information Leaflet	1	19 July 2010
Participant Consent Form		
Questionnaire: Outreach Patient Review Visit	1	19 July 2010
Questionnaire: Dental Student Baseline	1	19 July 2010
Questionnaire: Dental Student Post-Study	1	19 July 2010
Questionnaire: Outreach Supervisor Post-Study Feedback	1	19 July 2010
Questionnaire: Student clinic patient not wishing to participate	1	19 July 2010
CV - Dr David Monks		16 July 2010
CV - Dr William Henry Esler		
Evidence of insurance or indemnity		19 August 2009

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Dr Derek Richards intimated a conflict of interest in that he knew the CI and a number of the research team. This was not considered a material conflict of interest and it was agreed that Dr Richards could contribute to the discussion.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- ☐ Notifying substantial amendments
- ☐ Adding new sites and investigators
- ☐ Progress and safety reports
- ☐ Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.



Appendix 7

Patient Baseline Questionnaire



Dental Outreach Oral Hygiene Study

Outreach Patient Baseline Questionnaire



Dear clinic patient

This clinical trial aims to help us understand how best to deliver tooth cleaning instruction in our student clinics. This questionnaire asks a little about yourself and your thoughts on tooth cleaning. **There are no right or wrong answers.** All your answers will be held in confidence and anonymised.

Background Information (Tick answer which most closely represents you)

1. Are You? Male ☐ Female ☐
2. How old are you?
3. Do you smoke? Yes ☐ No ☐
4. When did you last receive dental treatment?
- Less than 1yr ago ☐ 1-3yrs ago ☐ Over 3yrs ago ☐

About your dental health (Tick answers which most closely represents you)

5. Do your gums ever **bleed** when you clean your teeth?
- Every time ☐ Occasionally ☐ Sometimes ☐ Seldom ☐ Never ☐
6. How **long** do you usually spend cleaning your teeth?
- Less than 30 seconds ☐ 30 seconds to 1min ☐ 1 min but under 2mins ☐ 2mins ☐ More than 2mins ☐
7. **After** brushing do you usually?
- Rinse with water ☐ Rinse with mouthwash ☐ Spit but do not rinse ☐

8. How often do you currently use the following? (Circle answer which most closely represents you)	More than twice a day	Twice a day	Once a day	Weekly	Occasionally	Seldom	Never
a) Manual toothbrush							
b) Electric toothbrush							
c) Floss							
d) Toothpicks/ woodsticks							
e) Brushes for between your teeth (Tepe or similar)							
f) Mouthwash							

9. How confident are you that you can: (Please circle the answer you think most nearly applies to you)	Not at All Confident				Extremely Confident		
a) Follow advice from the dental students about cleaning your teeth	1	2	3	4	5	6	7
b) Clean your teeth so that your teeth can't get any cleaner	1	2	3	4	5	6	7
c) Clean your teeth as often as you should	1	2	3	4	5	6	7
d) Clean your teeth for as long as you should	1	2	3	4	5	6	7
e) Clean your teeth the way you should	1	2	3	4	5	6	7

10. Please circle the answer you think most nearly applies to you	Strongly Agree				Strongly Disagree		
a) I always find it easy to follow advice from the students about cleaning my teeth	1	2	3	4	5	6	7
b) I would always like to clean my teeth until they can't get any cleaner, but I don't think it's possible for me to do so	1	2	3	4	5	6	7
c) I would like to clean my teeth as often as I should, but I don't think it's possible for me to do so	1	2	3	4	5	6	7
d) I would like to clean my teeth for as long as I should, but I don't think it's possible for me to do so	1	2	3	4	5	6	7
e) I would like to clean my teeth the way I should, but I don't think it's possible for me to do so	1	2	3	4	5	6	7

11. Please circle the answer you think most nearly applies to you	Strongly Agree				Strongly Disagree		
a) Cleaning my teeth is a good thing to do	1	2	3	4	5	6	7
b) Cleaning my teeth is a boring thing to do	1	2	3	4	5	6	7
c) Cleaning my teeth makes my mouth feel good	1	2	3	4	5	6	7
d) The more I clean my teeth, the less decay I will get	1	2	3	4	5	6	7
e) The more I clean my teeth, the less gum disease I will get	1	2	3	4	5	6	7
f) The longer I clean my teeth, the less decay I will get	1	2	3	4	5	6	7
g) The longer I clean my teeth, the less gum disease I will get	1	2	3	4	5	6	7
h) The longer I clean my teeth, the less my gums will bleed	1	2	3	4	5	6	7
i) The more I clean my teeth, the less my gums will bleed	1	2	3	4	5	6	7

12. Please circle the answer you think most nearly applies to you	Strongly Agree				Strongly Disagree		
a) I think the dental students want me to clean my teeth differently from how I now clean them	1	2	3	4	5	6	7
b) I don't care how the dental students think I should clean my teeth	1	2	3	4	5	6	7

13. How important are the following things to you: (Please circle the answer you think most nearly applies to you)	Not at All Important				Extremely Important		
a) The students take time with me	1	2	3	4	5	6	7
b) I get fillings done before anything else	1	2	3	4	5	6	7
c) I get my gums treated before anything else	1	2	3	4	5	6	7
d) My appointments are as short as possible	1	2	3	4	5	6	7
e) The students do lots of treatment at each appointment so I don't have to come back as many times	1	2	3	4	5	6	7
f) I receive preventive advice before anything else	1	2	3	4	5	6	7
g) I have my usual treatment as well as research carried out at the same appointment	1	2	3	4	5	6	7

14. Do you intend to participate in the study?

Yes ☐

No ☐

Don't know ☐

If you would like to expand on any of your answers or would like to comment about any part of the study, please use the box below:

Thank you for your time – please return to the researcher

Appendix 8

Patient Letter of Invitation and Information Pack



Dear Dental Outreach Patient

Dental Outreach Oral Hygiene Study

The outreach clinics are involved in a clinical study investigating the effect of preventative advice and instruction for outreach patients. This study is being conducted by NHS Education for Scotland and the Scottish Dental Practice Based Research Network, in collaboration with the University of Dundee

When you attend for your dental outreach appointment your student, together with supervising outreach staff, will discuss the study with you and invite you to take part. We have enclosed an information sheet about the study and would be grateful if you would read this before your next appointment.

If anything in the information sheet is not clear or if you would like any more information please do not hesitate to contact the research team for further information:

**Kerry Richardson, Principal Researcher,
Dundee Dental Education Centre (DDEC), Frankland Building, University of Dundee,
Dundee, DD1 4HN
k.n.richardson@dundee.ac.uk**

Yours sincerely

Kerry Richardson
Principal Researcher
Dental Outreach Oral Hygiene Study



Patient Invitation Letter
10/10/11/2010



We anticipate the trial to be interesting and exciting for all involved. The results of the trial will go forward inform outreach clinical practice and future student teaching.



Contact Information:

Lead Researcher:

Kerry Richardson
Restorative Dental Department
NES, Frankland Building
University of Dundee
Dundee, DD1 4HN

Tel: 01382 420073
k.n.richardson@dundee.ac.uk



Information Leaflet V3: 3rd November 2010



Dental Outreach Oral Hygiene Study



Dental Outreach Preventive Oral Care Study

Dental decay and gum disease can be prevented by effective tooth cleaning.

It is never too late to prevent new decay and improve gum health.

All adult dental outreach patients who are currently under treatment in outreach facilities are invited to participate in the **first ever outreach clinical trial**.



What would I have to do?

Each participant will complete a questionnaire and have their gum health measured during a normal appointment. They will then receive some advice on tooth cleaning and make an appointment to return.

Would this involve extra appointments?

Possibly. Participants will attend after three and then again in six months time to have their gums re-examined, and complete a short questionnaire.

If your current course of treatment is ongoing during this time, then the measurements may be completed during scheduled appointments.

Information Leaflet V3.3rd November 2010

Do I have to take part?

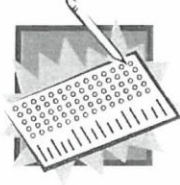
No. If you don't wish to take part, that is not a problem. You will still receive treatment on the clinic as normal.

I want to take part, what happens next?

Speak to supervisors on the clinic and your dental student. They will discuss the trial with you and will complete necessary consent procedures.

Can I change my mind?

If you enter the trial, you are subsequently free to withdraw your participation if you require. We however would like as many people to complete the trial to ensure an accurate picture.



As outreach clinics are a new dental care environment, we are interested in which ways are best for delivering treatment. Finding out which treatments work most effectively for you, our outreach patients.

We would like to invite you to take part in the first ever clinical trial in outreach. This trial will not only provide information about which preventive methods are better for outreach, but also give our students valuable experience in participating in clinical research.

Dental Outreach Oral Hygiene Study

Participant Information Sheet

Introduction

My Name is Dr Kerry Richardson and I am a PhD student at the University of Dundee. I am investigating the feasibility of clinical research in dental outreach clinics. I am inviting you to take part in a clinical study which is part of my PhD. Before you decide to participate in the study I need to ensure you understand why I am doing it and what it would involve if you agree. I am providing the following information. Please take time to read this information sheet carefully and be sure to ask any questions you wish. You may also like to discuss it with friends, and family. I will do my best to explain the project to you and provide you with any further information you wish.

What is the reason for this study?

Dental diseases are caused by dental plaque; regular removal of this, by effective tooth cleaning, prevents gum disease and dental decay. Our dental students regularly teach patients how to care for teeth and gums. We wish to find out whether the instruction our students deliver to their outreach patients improves the health of our patients' teeth and gums.

What is the purpose of the study?

This study will investigate whether a new method of teaching tooth cleaning is more effective than the traditional way.

Why have I been invited?

You have been invited to take part as you are attending an Outreach clinic attached to the University of Dundee, who are the Sponsors of this study.

Do I have to take part?

It is up to you to decide. We will describe the study to you and go over this information sheet, which is yours to keep. If you wish to take part, we will then ask you to sign a consent form to show you have agreed to participate. You are free to withdraw at any time, without giving any reason. Withdrawal would not affect the standard of care you receive.

What will I have to do?

At your routine appointment, before being examined you will complete a short questionnaire about tooth cleaning, you will have your gums examined by a final year dental student. You will then receive some tooth cleaning instruction dependent on the student group allocation; this could be the new method or the control instruction. In approximately three months you will return to the clinic to have your gums re-examined, and fill in another questionnaire. When you return for a final visit, at six months your gums will be examined one last time, and you will complete a final questionnaire.

How long will I be involved for?

You will be enrolled for six months in this study. During this time you will still receive normal dental care at the clinic as usual.

Can anyone take part?

Adult patients (over 16 years) will be invited. If you are pregnant, have no natural teeth, or have a medical problem which prevents examination of your gums we unfortunately cannot include you in this study. If you are found to have completely healthy gums you may also not be eligible for inclusion.

What are the risks of the study?

Since toothbrushing instruction is something which is already delivered during dental care there are no additional risks in being involved in the study.

Are there any benefits for me in being involved?

We would hope you will learn how to improve your oral health through prevention. Regular, effective tooth cleaning has been proven to prevent dental decay and reduce gum disease.

Do I have to take part?

No. If you do not wish to be involved in the study, please simply advise the researcher or clinic staff. You do not need to give a reason. You will of course still receive your usual dental care from the student clinic which may or may not include preventive instruction.

What if I change my mind?

Once you are enrolled in the study, you may withdraw if you feel it necessary. If you wish to do this please let the staff or researcher know. If you become pregnant during the study, please also advise the research team.

What will happen when the study is over?

When the study is over the results will be carefully examined. The findings will be used to inform student teaching not only at this centre but at other University of Dundee Outreach clinics.

Will anyone know my results?

No. Your personal results are completely confidential. You will receive a code so we can correctly calculate results. This will only be known after the gum scores are recorded so the research is as accurate as possible.

Will I be told my results?

Due to the confidentiality and coding, we will not be able to inform individual patients of their results. The results of the groups will be put together to gain an overall picture. After analysis, the completed study results will be reported to Outreach staff.

If you are interested in your personal gum health, please ask staff or students during your routine appointments, you do not have to be involved in the study to do this.

Will any of my plaque be stored and used for research in the future?

No

Will the information be published?

Yes, it is hoped that the study results will be published in journals. Results will be put together for analysis before publication. Individual patient data will not be published with the exception of quotes. You can be assured that any quotes from patient questionnaires completed during the study will be anonymised prior to publication.

This is specified in the patient consent form.

Is there a payment for taking part in the study?

No, just as the treatment you usually receive is free. The student clinic is unable to financially compensate you for your involvement in the study. We would be delighted if you wish to be involved and you may find that you learn a bit more about caring for your

Can anyone take part?

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Is there a payment for taking part in the study?

No, just as the treatment you usually receive is free. The student clinic is unable to financially compensate you for your involvement in the study. We would be delighted if you wish to be involved and you may find that you learn a bit more about caring for your

teeth. If however you receive travel expenses to help you attend for dental treatment you should be able to claim these through the usual means for study appointments (the appointments will be part of usual dental care).

Will my taking part in the study be kept confidential?

The information collected about you in this study will be anonymised i.e. linked to a special code that is stored separately on a password-protected computer file. Your identity will only be known to members of the research team within the Dental School at the University of Dundee. No one outside the research team will have any access to any identifying information. All identifiable information and the data will be kept secure.

Who is organizing and coordinating the study?

This study is being coordinated by The Dental School, University of Dundee. The Research Ethics Service, that has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS health boards.

Is the study safe?

Fife and Forth Valley Research Ethics Committee, which has responsibility for scrutinising proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research together with any relevant medical records, be made available for scrutiny by monitors from the university of Dundee and NHS Fife, whose role it is to check that research is properly conducted and the interests of those taking part are adequately protected.

If you believe that you have been harmed in any way by taking part in this study you have the right to pursue a complaint and seek any resulting compensation through the University of Dundee, who are acting as the research sponsor. Details about this are available from University of Dundee Dental Hospital and School, Park Place, Dundee, DD1 4HN. Also as a patient of the NHS you have a right to pursue a complaint through the usual NHS process. To do so you can submit a written complaint to: Fife NHS Board, Hayfield House, Hayfield Road, Kirkcaldy, Fife, KY2 5AH.

Note that the NHS has no legal liability for non-negligent harm. However if you are harmed and this is due to someone's negligence, you may have grounds for legal action against NHS Fife, but you may have to pay your legal costs.

What if I have other questions?

We are happy to answer questions about the project. Please feel free to contact the lead researcher:

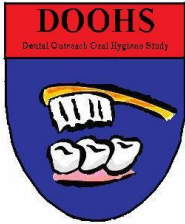
Kerry Richardson, Principal Researcher
University of Dundee, Dundee Dental Education Centre (DDEC)
Frankland Building, Dundee, DD1 4HN
Contact Telephone: 01382 420073
k.n.richardson@dundee.ac.uk

Thank you for taking the time to read this information and for considering taking part in this study.

Appendix 9

Case Report Form

DOOHS site:	Participant Identification no:	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>									Participant initials:	<table border="1"> <tr> <td></td><td></td><td></td><td></td> </tr> </table>				

<p align="center">CASE REPORT FORM</p> <p align="center">Dental Outreach Oral Hygiene Study</p> <p align="center">Study reference number REC 10/SO501/43</p>	
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<p align="center">SPONSOR: University of Dundee</p> <p align="center">PRINCIPAL INVESTIGATOR: Dr A.F. Hall</p>
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Participant Initials:	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>								
Subject Randomisation Number:	<table border="1"> <tr> <td><i>Student number</i></td> <td><i>Site number</i></td> <td><i>Patient number</i></td> </tr> <tr> <td></td> <td></td> <td></td> </tr> </table>	<i>Student number</i>	<i>Site number</i>	<i>Patient number</i>					
<i>Student number</i>	<i>Site number</i>	<i>Patient number</i>							
	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>								
Research Site (Outreach Centre)									

<p align="center">I am confident that the information supplied in this case record form is complete and accurate data. I confirm that, to my knowledge, the study was conducted in accordance with the protocol and any protocol amendments and that written informed consent was obtained prior to the study.</p>																				
Baseline Visit:																				
Supervisor's Signature:	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>																			
Date of signature:																				
	d	d	m	m	m	y	y	y	y											

DOOHS site:	Participant Identification no:	<table><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>							Participant initials:	<table><tr><td></td><td></td><td></td></tr></table>			

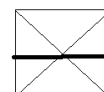
3 Month Review Visit:											
Supervisor's Signature:											
Date of signature:											
		d	d	m	m	m	y	y	y		
6 Month Review Visit:											
Supervisor's Signature:											
Date of signature:											
		d	d	m	m	m	y	y	y		

DOOHS site:	Participant Identification no:	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>							Participant initials:	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			

Notes for completing this Case Report File

This file records the participant's clinical research information. It is confidential and must **not** be removed from the research site. Please ensure it is completed at every study visit. It is extremely important that the areas requiring codes and signatures are completed by the researcher or supervisor once each procedure has been carried out. To maintain blinding, student researchers must only use their code throughout this CRF, (not name or sign it).

Plaque and Bleeding charts are recorded on the dichotomous O'Leary charting system. If a tooth is missing please place a horizontal line through the tooth as follows:



To record plaque and bleeding scores the triangles should be marked in the usual manner, it is **not** however essential to do this in colour, a black pen is sufficient. If a mesial or distal surface has plaque, remember to record the adjacent side of the contact (unless there is a space).



Please use a calculator to help with the calculations, (you can find one in the accessories area of the computer). Please see example below:

VISIT 1 (SCREENING)

Date: 01 01 2001
DD MM YYYY

Upper Right

Lower Right

Plaque Chart

Upper Left

18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
[Horizontal line]				[Triangle]		[Triangle]		[Triangle]		[Triangle]		[Horizontal line]			
48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
[Horizontal line]				[Triangle]		[Triangle]		[Triangle]		[Triangle]		[Horizontal line]			

Lower Left

Number of sites (total number of teeth x 4) 72

Number of sites with Plaque -28 -

39 %Plaque

Completed charts must be removed from the CRF and placed in the box in the clinic this maintains blinding at review visits. **Please ensure the chart has the participant's identification code before detaching from the CRF.**

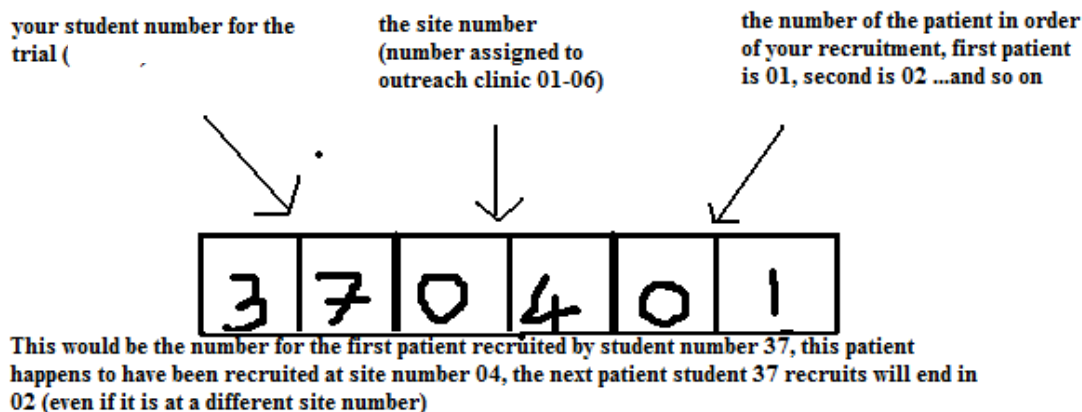
DOOHS site:	Participant Identification no:	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>							Participant initials:	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			

Questionnaires

There are questionnaire reminders in the CRF. Your participant should have already received the Baseline questionnaire to complete at home. If it has been completed please sign it off in the area. If they did not receive this in advance of the appointment it is essential they complete this **before** the plaque and bleeding charts are recorded. As it is **confidential**, if your patient is required to complete this in the dental chair (i.e. they did not complete this either at home or in the waiting room), please do leave them to do this **without observation**.

It is **essential** you write the **participant's identification number** on the front of this file and complete the CRF identification sheet, please attach the relevant identification sheet securely to the questionnaires by stapling through the questionnaire.

Remember the identification number is assigned by the **baseline** investigator as follows:



The number is retained by the participant for the duration of the study. It needs to be recorded in the site file. Please remember that you also need to keep a record of the patients you recruit during the study. With regards to initial boxes, if a participant does not have a middle initial please put a line through the central box.

Please complete the participant randomisation log. Ensure all participants have the **DOOHS alert on their R4 notes** and that the study visit is clear in R4. In R4, you should write *"Baseline study visit, consent taken, questionnaire completed, plaque and bleeding charts carried out, OHI given" ID code (-----), review arranged* no further details and do **not** put your name on the notes, use your researcher number. For review visits e.g. *"3/12 review, PMH no change, whether or not there have been any adverse events, questionnaire completed, charts carried out, next review arranged"*

If there are any problems please check with your supervisor.

DOOHS site:	Participant Identification no:	<div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	Participant initials:	<div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>
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<i>Please ensure all items listed are completed for the relevant visit and write your code to confirm</i>			
Patient Visit	Item completed	Investigator code	Date
Baseline Visit	Eligibility		
	Consent		
	Patient Baseline Questionnaire		
	Plaque chart		
	Bleeding chart		
	OHI Delivery		
3 month Review	Plaque and Bleeding charts		
	Enquired about adverse events		
	Patient Review Questionnaire		
6 month Review	Plaque and Bleeding charts		
	Enquired about adverse events		
	Patient Review Questionnaire		

DOOHS site:	Participant Identification no:	<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	Participant initials:	<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>
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Inclusion Criteria

	<u>Yes</u>	<u>No*</u>
1 Is the subject an adult patient (16 years or over)?	<input style="width: 50px; height: 25px;" type="checkbox"/>	<input style="width: 50px; height: 25px;" type="checkbox"/>
2 Is the subject dentate or partially dentate?	<input style="width: 50px; height: 25px;" type="checkbox"/>	<input style="width: 50px; height: 25px;" type="checkbox"/>
3 Is the general health of the subject good?	<input style="width: 50px; height: 25px;" type="checkbox"/>	<input style="width: 50px; height: 25px;" type="checkbox"/>
4 Has the subject willingly given written informed consent?	<input style="width: 50px; height: 25px;" type="checkbox"/>	<input style="width: 50px; height: 25px;" type="checkbox"/>

*If any inclusion criteria are ticked no then the patient is not eligible for the study.

Exclusion Criteria

	<u>Yes*</u>	<u>No</u>
1 Does the medical history contraindicate periodontal examination? (e.g. known bleeding disorder)	<input style="width: 50px; height: 25px;" type="checkbox"/>	<input style="width: 50px; height: 25px;" type="checkbox"/>
2 Does the subject have completely healthy gums and no dental plaque?	<input style="width: 50px; height: 25px;" type="checkbox"/>	<input style="width: 50px; height: 25px;" type="checkbox"/>
3 Is the subject completely edentulous?	<input style="width: 50px; height: 25px;" type="checkbox"/>	<input style="width: 50px; height: 25px;" type="checkbox"/>
4 Is the subject pregnant?	<input style="width: 50px; height: 25px;" type="checkbox"/>	<input style="width: 50px; height: 25px;" type="checkbox"/>
5 Is the subject aged under 16 years?	<input style="width: 50px; height: 25px;" type="checkbox"/>	<input style="width: 50px; height: 25px;" type="checkbox"/>

* If any exclusion criteria are ticked yes then the patient is not eligible for the study.

INFORMED CONSENT

Please note: written informed consent must be given before any study specific procedures take place.

Has the subject freely given written informed consent?

Yes ☐ No ☐

DOOHS site:	Participant Identification no:	<table border="1" style="width: 100%; height: 30px; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> </tr> </table>							Subject initials:	<table border="1" style="width: 100%; height: 30px; border-collapse: collapse;"> <tr> <td style="width: 33%;"></td> <td style="width: 33%;"></td> <td style="width: 33%;"></td> </tr> </table>			

Patient Baseline Questionnaire

Participant Identification Number:

(Student number)		(Site number)		(Recruitment number)	

Please ensure this sheet is completed and attached securely
to the front of the patient baseline questionnaire

PLEASE TURN PAGE AND COMPLETE CLINICAL MEASUREMENTS

[illegible]

Lower Right
Lower Left

Number of sites with bleeding _____

Number of sites (total number of teeth x 4) _____

Comments:

Any other treatment completed at this visit?

--

--

Please ensure participant ID is on the page, detach this page and place in research box in clinic.

DOOHS site:	Participant Identification no:	<table border="1" style="width: 100%; height: 30px; border-collapse: collapse;"> <tr> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> </tr> </table>							Subject initials:	<table border="1" style="width: 100%; height: 30px; border-collapse: collapse;"> <tr> <td style="width: 33%;"></td> <td style="width: 33%;"></td> <td style="width: 33%;"></td> </tr> </table>			

Patient Review Questionnaire 3/12

Participant Identification Number:

(Student number)		(Site number)		(Recruitment number)	

Please ensure this sheet is completed and attached securely to the front of the patient review questionnaire

PLEASE TURN PAGE AND COMPLETE CLINICAL MEASUREMENTS

DOOHS site:	Participant Identification no:	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>							Subject initials:	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> <td style="width: 30px; height: 20px;"></td> </tr> </table>			

Please ensure Review Questionnaire is completed at this visit

3 Month Review Visit

Date: _____ -

DD MM

YYYY

Plaque Chart

Upper Right
Upper Left

18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Lower Right
Lower Left

Number of sites with Plaque _____

Number of sites (total number of teeth x 4) _____

Bleeding on Marginal Probing

Upper Right
Upper Left

18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Lower Right
Lower Left

Number of sites with bleeding _____

Number of sites (total number of teeth x 4) _____

Comments:

Any other treatment completed at this visit?

--

--

line for each condition.

Please ensure participant ID is on the page, detach this page and place in research box in clinic.

DOOHS site:	Participant Identification no:	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>							Subject initials:	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			

Please ensure Review Questionnaire is completed at this visit

6 Month Review Visit

Date: _____

DD MM

YYYY

Plaque Chart

Upper Right
Upper Left

18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38

Lower Right
Lower Left

Number of sites with Plaque _____

Number of sites (total number of teeth x 4) _____

bing

Upper Right
Upper Left

18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38

Lower Right
Lower Left

Number of sites with bleeding _____

Number of sites (total number of teeth x 4) _____

%BOMP

Comments:

Any other treatment completed at this visit?

DOOHS site:

Participant
Identification
no:

--	--	--	--	--	--

Subject
initials:

--	--	--

Adverse Events

Has the patient experienced any Adverse Events since signing the Informed Consent?

☐ Yes, specify below☐ No

AE no.	Adverse Event (diagnosis (if known) or signs/symptoms)	Start Date dd/mm/yyyy and Time (24 hour clock)	Stop Date dd/mm/yyyy and Time (24 hour clock)	Outcome 1=Recovered 2=Recovered with sequelae 3=Continuing 4=Patient Died 5=Change in AE 6=unknown	Severity 1=Mild 2=Moderate 3=Severe	Plausible relationship to Intervention	Action taken 1=None 2=Advice only 3=Treatment for Dentine Hypersensitivity 4= Restoration required for brushing abrasion	Withdrawn due to AE?	Serious AE (SAE)?	If SAE does it require immediate reporting? (see Protocol)?
		/ / :	/ / :			<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
		/ / :	/ / :			<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
		/ / :	/ / :			<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

DOOHS site:	Participant Identification no:	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>									Subject initials:	<table border="1"><tr><td></td><td></td><td></td></tr></table>			

OFF STUDY FORM

Date Off Study: ____ / ____ / ____

(DD/MM/YYYY)

Date Last Study Visit: ____ / ____ / ____

(DD/MM/YYYY)

Reason Off Study (Please mark only the primary reason. Reasons **other than Completed Study** require explanation next to the response)

☐ Completed study

☐ AE/SAE (**complete AE CRF & SAE form, if applicable**)

☐ Lost to follow-
up_____

☐ Non-compliant
participant_____

☐ Medical
contraindication_____

☐ Withdraw
consent_____

☐ Death (**complete SAE
form**)_____

☐ Other

Appendix 10

University Sponsorship Confirmation



College of Medicine, Dentistry and Nursing

Division of Clinical & Population Sciences & Education

Director of Clinical & Population Sciences & Education
Professor Frank Sullivan PhD FRCP FRCGP

21 July 2010

APP No 00000053

Kerry Richardson
c/o Restorative Dental Department
Frankland Building
University of Dundee
DD1 4HN

Project Title: Improving oral hygiene inpatients attending primary care dental outreach facilities: through delivery of enhanced oral care hygiene instruction, framed using psychological theory

Dear

Sponsorship of Project

Under the requirements of the Scottish Executive Health Department's Research Governance Framework for Health and Community Care, the University of Dundee agrees in principle to act as sponsor for this project. This provisional Sponsorship is subject to you obtaining a favourable ethical opinion and appropriate local University & NHS R&D management approvals (if required).

As Chief Investigator, you must remember that you must not begin your project until all necessary approvals have been obtained. If the details of the project change, either during the process of obtaining these approvals, or during the project itself, you must notify Dr Davis immediately, and if appropriate the Ethics committee, and the relevant R&D offices.

Lastly, please make sure that you quote the Application Number given above in any correspondence.

Yours sincerely

Dr Julian P L Davis
Lecturer, Division of Clinical & Population Sciences & Education
t 01382 420104
e j.p.l.davis@cpse.dundee.ac.uk

Appendix 11

Health Board R&D Approval Letters



Dr Donald McHutcheon
Senior Dental Officer
Willow Drive Dental Access Centre
11-15 Willow Drive
KIRKCALDY KY1 2LF

Medical Director, Primary Care
Room 313
Hayfield House
Hayfield Road
KIRKCALDY
Fife KY2 5AH
Tel 01592 643355
www.show.scot.nhs.uk/fpct

Date 2 November 2010
Our Ref 10-045 10/S0501/43
NRS10/DN07
Enquiries to Aileen Yell
Tel No 01383 565110
Email aileen.yell@nhs.net

Dear Dr McHutcheon

Project Title: Dental Outreach Oral Hygiene Study

Thank you for your application to carry out the above project. Your project documentation (detailed below) has been reviewed for resource and financial implications for NHS Fife and I am happy to inform you that Management Approval has been granted.

Approved documents

Document	Version	Date
Protocol	1	19 July 2009
IRAS REC form	3.0	19 July 2009
CV – Dr D McHutcheon		3 August 2010
REC provisional favourable opinion letter		10 August 2010
REC final favourable opinion letter		3 September 2010
IRAS SSI Form	3.0	13 October 2010
NRS-CC Certificate of Compliance		5 October 2010
Site Specific Assessment Review		29 October 2010

The terms of the approval states that the investigators authorised to undertake this study within NHS Fife are Dr D McHutcheon and Dr L Wheatley.

A Site Specific Assessment review has been carried out by NHS Fife R&D office on 29 October 2010. A copy of your GCP Certificate (once available) and signed copy CV were requested by e-mail on the same date.

The sponsors for this study are the University of Dundee.

Details of our participation in studies will be included in annual returns we are expected to complete as part of our agreement with the Chief Scientist Office. Regular reports of the study require to be submitted. Your first report should be submitted to Dr A Wood, R&D Manager, R&D Resource Centre, Lynebank Hospital, Halbeath Rd, Dunfermline, KY11 4UW (Amanda.wood3@nhs.net) in 12 months time and subsequently at yearly intervals until the work is completed. A Lay Summary will also be required upon completion of the project.

In addition, approval is granted subject to the following conditions:-

Research and Development

Foresterhill House Annexe
Foresterhill
Aberdeen
AB25 2ZB



Dr Andrew McIntosh
Senior Dental Officer
Aberdeen Dental Outreach
Cornhill Road
Aberdeen
AB25 2ZN

Date 13/10/10
Our Ref 2010MD004
Enquiries to
Extension 51121
Direct Line 01224 551121

Dear Dr McIntosh

Management Approval for Non-Commercial Research

MREC Ref: 10/S0501/43
NRS Ref: NRS10/DN07
Project title: Improving Oral Hygiene in Patients Attending Primary Care Dental Outreach Facilities: Through Delivery of Enhanced Oral Hygiene Instruction, Framed using Psychological Theory

Thank you very much for sending all relevant documentation. I am pleased to confirm that the above project is now registered with the NHS Grampian Research & Development Office. The project now has R & D Management Approval to proceed locally. This is based on the documents received from yourself and the relevant Approvals being in place.

All research with an NHS element is subject to the Research Governance Framework for Health and Community Care (2006, 2nd edition), and as Chief or Principal Investigator you should be fully committed to your responsibilities associated with this.

It is particularly important that you inform us when the study terminates.

The R&D Office must be notified immediately and any relevant documents forwarded to us if any of the following occur:

- A change of Principal Investigator, Chief Investigator or any additional research personnel
- Premature project termination
- Any amendments (particularly a study extension)
- Any change to funding or any additional funding
- Any Serious Adverse Events

We hope the project goes well, and if you need any help or advice relating to your R&D Management Approval, please do not hesitate to contact the office.

Yours sincerely

A handwritten signature in black ink, appearing to read 'S. Ridge', with a stylized flourish at the end.

Susan Ridge
Business Development Officer

Cc: Dr Andrew Hall, Chief Investigator, University of Dundee Dental School
NHS Research Scotland Permissions Co-ordinating Centre (NRS Permissions CC)

Prof David J Godden, MD, FRCP(Edn), FRCP(Glasg)
Research Director
NHS Highland Research Office
Room S101
The Centre for Health Science
Old Perth Road
Inverness, IV2 3JH

Tel: 01463 255823
Fax: Not available
E-mail: david.godden@nhs.net



12 October 2010

NHS Highland R&D ID: 691
NRSPCC ID: NRS10/DN07

Dr David Monks
Senior Dental Officer
Inverness Dental Centre
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH

Dear Dr Monks,

Management Approval for Non-Commercial Research

I am pleased to tell you that you now have Management Approval for the research project entitled: **'Improving Oral Hygiene in Patients Attending Primary Care Dental Outreach Facilities: Through Delivery of Enhanced Oral Hygiene Instruction, Framed using Psychological Theory'**. I acknowledge that:

- The project is sponsored by the University of Dundee.
- The project does not have external funding.
- Research Ethics approval for the project has been obtained from the East of Scotland Research Ethics Committee, (Reference Number: 10/S0501/43).
- The Site-Specific Information form for this site has been reviewed (completed on 27/09/10) and there is no objection to NHS Highland being included as a site for this project

The following conditions apply:

- The responsibility for monitoring and auditing this project lies with the University of Dundee.

Working with you to make Highland the healthy place to be

Headquarters:
NHS Highland, Assynt House, Beechwood Park, Inverness, IV2 3HG

Chairman: Mr Garry Coutts
Chief Executive: Dr Roger Gibbins BA MBA PhD
Highland NHS Board is the common name of Highland Health Board



- This study will be subject to ongoing monitoring for Research Governance purposes and may be audited to ensure compliance with the Research Governance Framework for Health and Community Care in Scotland (2006, 2nd Edition), however prior written notice of audit will be given.
- **Two members of the research team MAY require an NHS Highland Honorary Research Contract prior to starting the project at this site. Dr Andrew Hall and Ms Kerry Richardson may need an HRC, but this will be dependent on existing contracts and whether a Research Passport is held by Dr Hall. Once this issue is resolved, research may start at this site.**
- All amendments (minor or substantial) to the protocol or to the REC application should be copied to the NHS Highland Research and Development Office together with a copy of the corresponding approval letter. All such amendments will be covered by the approval given by this letter, and it is therefore not necessary to seek amendment approval.
- The paperwork concerning all incidents, adverse events and serious adverse events, thought to be attributable to participant's involvement in this project should be copied to the NHS Highland R&D Office.
- Monthly recruitment rates should be notified to the NHS Highland Research and Development Office, detailing date of recruitment and the participant trial ID number. This should be done by e-mail on the first week of the following month.

Please report the information detailed above, or any other changes in resources used, or staff involved in the project, to the NHS Highland Research and Development Manager, Frances Hines (01463 255822, frances.hines@nhs.net).

Yours sincerely,



Mr Angus Watson
Research and Development Director

cc Frances Hines, R&D Manager, NHS Highland Research & Development Office, Room S101, The Centre for Health Science, Old Perth Road, Inverness, IV2 3JH
Pamela Smith, Senior Administrator, NHS Research Scotland Coordinating Centre, Research & Development Office, Foresterhill House Annexe, Foresterhill, Aberdeen, AB25 2ZB
Dr Andrew Hall, Senior Lecturer/Honorary Consultant in Restorative Dentistry, University of Dundee Dental School, Frankland Building, Smalls Wynd, Dundee, DD1 4HN.

EC/LH

21 October 2010

Dr Andrew Hall
Senior Lecturer
University of Dundee Dental School
Frankland Building
Smalls Wynd
DUNDEE
DD1 4HN

Dear Dr Hall,

NHS TAYSIDE MANAGEMENT/GOVERNANCE APPROVAL

NRS Project ID: NRS10/DN07

Tayside R&D Project ID: 2010DE13

Title: Improving Oral Hygiene in Patients Attending Primary Care Dental Outreach Facilities:
Through Delivery of Enhanced Oral Hygiene Instruction, Framed using Psychological Theory.

Main REC Ref: 10/S0501/43 Main REC Approval Date: 10/08/10

Funder: Unfunded

Sponsor: University of Dundee

NHS Support Costs: Yes

The above project has been registered on the NHS Tayside R&D database, as required by the Research Governance Framework. Full ethical approval has been obtained and there are local NHS Support Costs associated with this research project.

NHS Tayside has no objection to the project proceeding, provided all necessary approvals are in place and all amendments to the protocol, personnel involved and funding be notified to the R&D Office and all appropriate personnel. Please note notification of end of study and a copy of the end of study report is also required by the NHS R&D office.

It is important to note that all research must be carried out in compliance with the Research Governance Framework for Health & Community Care, GCP and the new EU Clinical Trials Directive (for clinical trials involving investigational medicinal products).

Kind Regards



Elizabeth Eno
R&D Manager

c.c. NRSPCC
Dr Kerry Richardson
Dr William Esler
Dr Susan Carson

Appendix 12

Research CV Example

CURRICULUM VITAE

Name:	
Kerry Richardson	
Present appointment: <i>(Job title, department, and organisation.)</i>	
PhD Student	
Address: <i>(Full work address.)</i>	
Dundee Dental Education Centre Frankland Building, Smalls Wynd Dundee, DD1 4HN	
Telephone number:	Email address:
07764686116	k.n.richardson@dundee.ac.uk
Qualifications:	
BDS (2001), MFDS RCS Edin. (2004)	
Professional registration: <i>(Name of body, registration number and date of registration.)</i>	
General Dental Council, Registration Number: 79659, date 1 st registration: July 2001	
Previous and other appointments: <i>(Include previous appointments in the last 5 years and other current appointments.)</i>	
PhD Student,	
Other current appointments	
Honorary contract for NHS Tayside Clinical Teacher for Outreach and Restorative Dental Department Dundee Dental School	
Previous appointments	
Senior Dental Officer for Outreach, NHS Tayside (May 08-Feb 09) Clinical Teacher Restorative Dental Department, Dundee Dental Hospital (Nov 06- April 08)	
Research experience: <i>(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)</i>	
Participation in Audit	
Research training: <i>(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)</i>	
Good Clinical Practice training 18 th March 2010 Consenting Patients for Clinical Trials lecture 17 th June 2010 Statistics for clinical researchers course (5 day course November/December 2009) Qualitative research courses (2 half days, November 2009)	
Relevant publications: <i>(Give references to all publications in the last two years plus other publications relevant to the current application.)</i>	
none	
<i>Other relevant publications</i>	
Signature:	Date:
	16 th July 2010

Appendix 13

TAHSC Introduction to Good Clinical Practice Questionnaire

Good Clinical Practice Training for Clinical Trials



1. Did you receive sufficient briefing about the course today?

Yes

No

Comments

2. Overall did the course meet your learning needs?

Yes

No

Partially

Comments

3. What subject was the most useful to you?

4. What subject was not useful to you?

5. Are there any areas you would like further training on?

6. How can we improve this GCP course?

7. Rate the overall usefulness of the course.

8. Have you received any GCP training before this course?

Additional comments

Appendix 14

DOOHS Short Training Film

This appendix can be accessed by using the QR Code below which will take you to the relevant presentation.



<https://uod.box.com/s/tsnd4ezcylwxspelvahbmsf34g4bz267>

Appendix 15

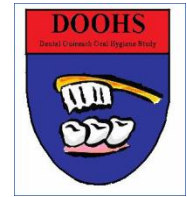
DOOHS Intervention Group Training

This appendix can be accessed by using the QR Code below which will take you to the relevant documentation..



<https://uod.box.com/s/tsnd4ezcylwxspelvahbmsf34g4bz267>

Dental Outreach Oral Hygiene Study



INTERVENTION GUIDANCE

Enhanced Advice

Current best evidence suggests that simple chair-side advice is effective in improving oral hygiene when framed using a psychological framework (Tell-Show-Do-Plan). The integration of **biomarker** will improve patient adherence to advice given.

Tell your patients where they have bleeding



Show them where the areas are.



Show them **how** to effectively clean these areas



Do ensure they can clean the areas for themselves



Plan that they will look for signs of disease and clean more carefully if they see signs.



- Discuss the usual key oral hygiene messages:
 - ❖ Brush teeth **twice** daily – once last thing at night and on one other occasion
 - ❖ Use **fluoride** toothpaste
 - ❖ Brush for **two** minutes.
 - ❖ Bleeding gums require **more careful** cleaning
 - ❖ **Spit** but do not rinse

While instructing your patients:

- Sit the patient upright, remove your mask and the patient's safety glasses, (if the patient usually wears their own glasses ask them to put them on).
- **Tell** the patient that you have discovered bleeding and/or plaque, and that bleeding is a sign of disease, or, if they have no bleeding, that plaque can cause tooth decay and gum problems.
- **Show** them in their mouth, using the hand mirror, areas where this is a problem (bleeding/plaque as per charts).
- **Show** them how to correctly clean these areas. (Please try not to use technical names for methods and angles, the focus is on them feeling and seeing the correct method.
- **Do** get them to demonstrate they can clean effectively in these areas.
- Do get them to feel how smooth clean teeth are if their charts displayed high plaque levels.
- **Do** ensure they understand bleeding means they need to brush **more carefully** in these areas.
- Plan that they will clean at two specific times of day
- **Plan** they will look for bleeding and clean these areas more carefully.
- Ask if there they have any questions.

Further Notes:

- Always be encouraging and positive, even if their toothbrushing technique is poor.
- If their technique is correct tell patients they are brushing in 'exactly the right way' and that you are confident they can 'keep on brushing as well as they did in the surgery' (*use your own words*).
- If their technique could be improved, please tell patients that they have 'done well' but that you have 'some suggestions for how they could do even better' (*again use your own words, the important point is that you are always positive and encouraging and **never negative** or **discouraging***).
- Ask patients whose technique needed improvement to demonstrate method of cleaning again.
- Once you are satisfied with the patients' technique, tell patients they are cleaning in exactly the right way and that you are confident they can 'keep on cleaning as well as they did in the surgery' (*use your own words*).
- Encourage patients to make a **plan** for when they will brush their teeth before they leave the surgery. The best way is to match tooth cleaning to something they already do every day e.g. before going to bed, after breakfast etc.

Appendix 16

Staff Training Feedback Questionnaire

Title of Course:	Good Clinical Practice (GCP) in Relation to Clinical Research in Dental Outreach	CPD Credits:	2		
Presenters:	Kerry Richardson	Sessions:			
Venue:	Inverness Dental Centre	Date:	23 rd November 2010		

Profession (please circle)

GDP VDP/GPT Other Dentist PCD Undergraduate Postgraduate

Dental Academic Laboratory Tech Other

1. The objectives of this Course were: Please tick the relevant box to indicate whether you think these objectives were met.

a. Good Clinical Practice in relation to clinical research in dental outreach	Yes		Partially		No	
b. Understand the Dental Outreach Oral Hygiene Study (DOOHS) documentation and protocol	Yes		Partially		No	
c. Understand how to provide support to dental students in during the study	Yes		Partially		No	
d. Understand how to consent patients in relation to clinical trials						

2. How would you rate the course as a whole:

Excellent	Good	Average	Below Average	Poor
------------------	-------------	----------------	----------------------	-------------

a. Overall content

b. Course presentation and design

c. Relevance to own educational needs

3. How would you rate the length of the course?

Too long **Too short** **About right**

4. What was the best feature of the course?

5. What would you have changed?

6. General Comments

7. Would you recommend a course like this to your colleagues?

Yes

No

8. Any other suggestions for Continuing Professional Development Courses?

Thank you for completing this form

Appendix 17

Participant 3/6 Month Review Questionnaire

11. How important are the following things to you. (Please circle the answer you think most nearly applies to you)	Not at All Important					Extremely Important				
a) The students take time with me	1	2	3	4	5	6	7			
b) I get fillings done before anything else	1	2	3	4	5	6	7			
c) I get my gums treated before anything else	1	2	3	4	5	6	7			
d) My appointments are as short as possible	1	2	3	4	5	6	7			
e) The students do lots of treatment at each appointment so I don't have to come back as many times	1	2	3	4	5	6	7			
f) I receive preventive advice before anything else	1	2	3	4	5	6	7			
g) I have my usual treatment as well as research carried out at the same appointment	1	2	3	4	5	6	7			

12. How was your overall research experience? (Please circle the answer you think most nearly applies to you)	Strongly Agree					Strongly Disagree				
a) The students took time to explain things	1	2	3	4	5	6	7			
b) I had opportunity to ask questions	1	2	3	4	5	6	7			
c) The supervisor checked the student's work	1	2	3	4	5	6	7			
d) The student seemed confident	1	2	3	4	5	6	7			
e) The student was enthusiastic	1	2	3	4	5	6	7			
f) The staff was enthusiastic	1	2	3	4	5	6	7			
g) The student explained things clearly	1	2	3	4	5	6	7			
h) It was easy to attend for this review appointment	1	2	3	4	5	6	7			
i) Overall the experience was interesting	1	2	3	4	5	6	7			
j) Overall the experience was enjoyable	1	2	3	4	5	6	7			
k) I would recommend participating to a friend	1	2	3	4	5	6	7			

If you would like to expand on any of your answers or would like to comment about any part of the study, please use the box below:

Thank you for your time – please return envelope to the researcher



Dental Outreach Oral Hygiene Study

Outreach Patient Review Visit Questionnaire

Dear clinic patient

Thank you for taking part in this study. We appreciate you taking the time to tell us about tooth cleaning thoughts. As previously, this questionnaire is completely anonymous and will only be seen by the research team, not by any of the staff or students on the clinic. Once you have finished, please seal it in the envelope provided and give to clinic staff.

1a. How long do you expect your appointment to take today? (Tick box which most closely represents you)

Shorter than usual ☐ Normal time ☐ Longer than usual ☐ Not sure ☐

1b. Do you expect to have any other treatment done today other than the gum health measurements?

Yes ☐ No ☐ Don't know ☐

2. Do you smoke?

Yes ☐ No ☐

About your dental health. (Tick box which most closely represents you)

3. Do your gums ever bleed when you clean your teeth?

Every time ☐ Occasionally ☐ Sometimes ☐ Seldom ☐ Never ☐

4. How long do you usually spend cleaning your teeth?

Less than 30 seconds ☐ 30 seconds to 1 min ☐ 1 min but under 2mins ☐ 2mins ☐ More than 2mins ☐

5. After brushing do you usually?

Rinse with water ☐ Rinse with mouthwash ☐ Spit but do not rinse ☐

6. How often do you currently use the following? (Tick answer which most closely represents you)	More than twice a day	Twice a day	Once a day	Weekly	Occasionally	Seldom	Never
a) Manual toothbrush	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Electric toothbrush	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Floss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Toothpicks/woodsticks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Brushes for between your teeth (Tape or similar)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Mouthwash	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. How confident are you that you can: (Please circle the answer you think most nearly applies to you)	Not at All Confident				Extremely Confident			
a) Follow advice from the dental students about cleaning your teeth	1	2	3	4	5	6	7	
b) Clean your teeth so that your teeth can't get any cleaner	1	2	3	4	5	6	7	
c) Clean your teeth as often as you should	1	2	3	4	5	6	7	
d) Clean your teeth for as long as you should	1	2	3	4	5	6	7	
e) Clean your teeth the way you should	1	2	3	4	5	6	7	

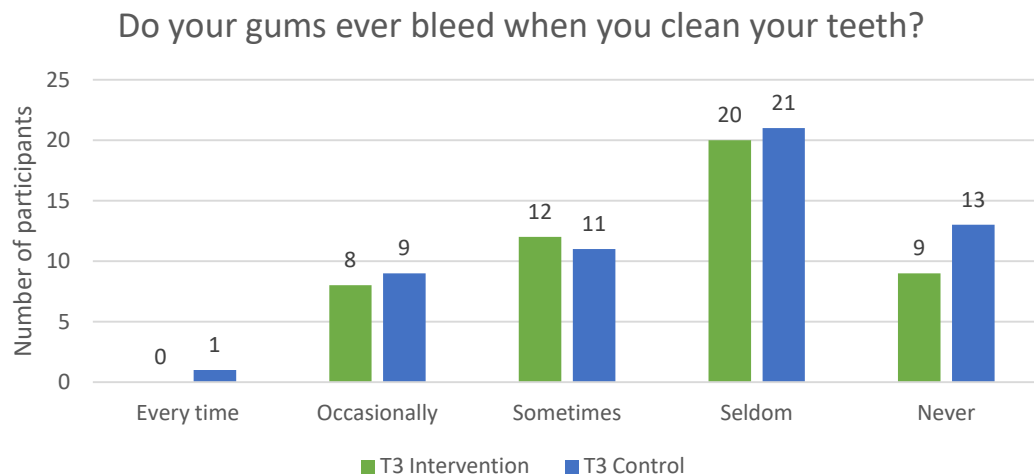
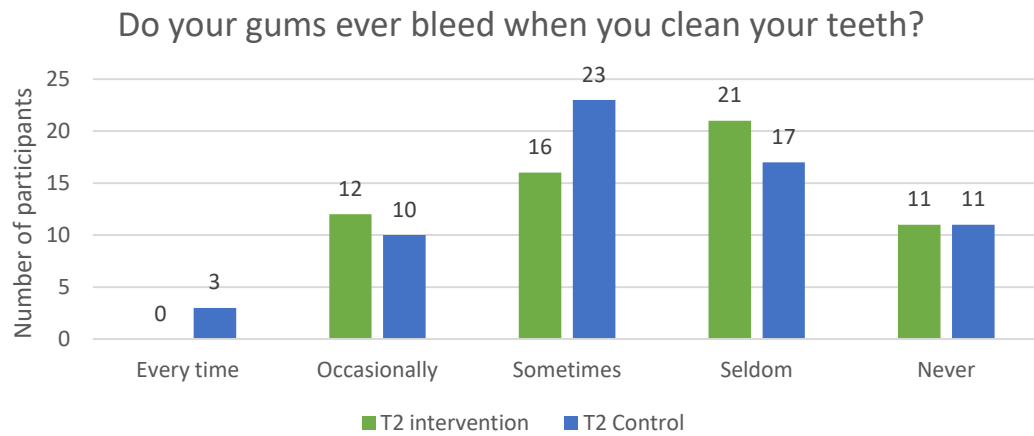
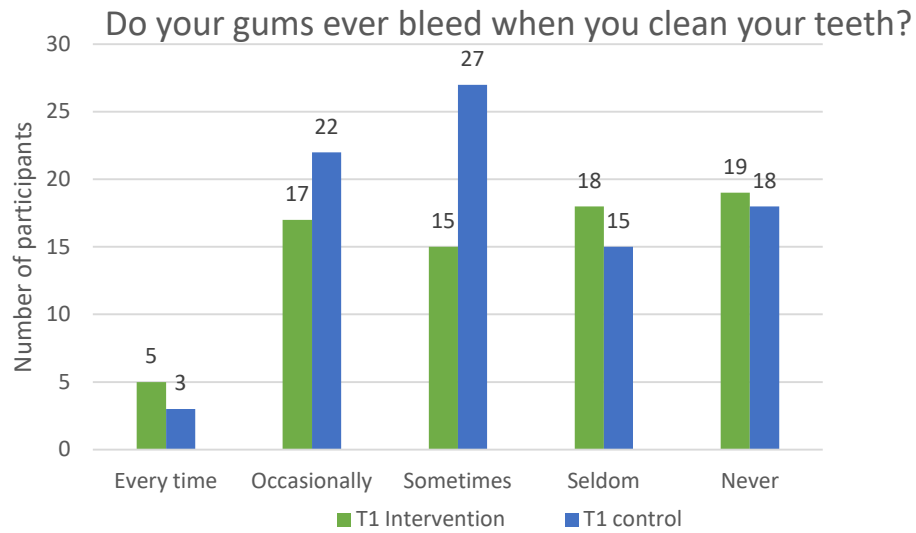
8. Please circle the answer you think most nearly applies to you	Strongly Agree				Strongly Disagree			
a) I always find it easy to follow advice from the students about cleaning my teeth	1	2	3	4	5	6	7	
b) I would always like to clean my teeth until they can't get any cleaner, but I don't think it's possible for me to do so	1	2	3	4	5	6	7	
c) I would like to clean my teeth as often as I should, but I don't think it's possible for me to do so	1	2	3	4	5	6	7	
d) I would like to clean my teeth for as long as I should, but I don't think it's possible for me to do so	1	2	3	4	5	6	7	
e) I would like to clean my teeth the way I should, but I don't think it's possible for me to do so	1	2	3	4	5	6	7	

9. Please circle the answer you think most nearly applies to you	Strongly Agree				Strongly Disagree			
a) Cleaning my teeth is a good thing to do	1	2	3	4	5	6	7	
b) Cleaning my teeth is a boring thing to do	1	2	3	4	5	6	7	
c) Cleaning my teeth makes my mouth feel good	1	2	3	4	5	6	7	
d) The more I clean my teeth, the less decay I will get	1	2	3	4	5	6	7	
e) The more I clean my teeth, the less gum disease I will get	1	2	3	4	5	6	7	
f) The longer I clean my teeth, the less decay I will get	1	2	3	4	5	6	7	
g) The longer I clean my teeth, the less gum disease I will get	1	2	3	4	5	6	7	
h) The longer I clean my teeth, the less my gums will bleed	1	2	3	4	5	6	7	
i) The more I clean my teeth, the less my gums will bleed	1	2	3	4	5	6	7	

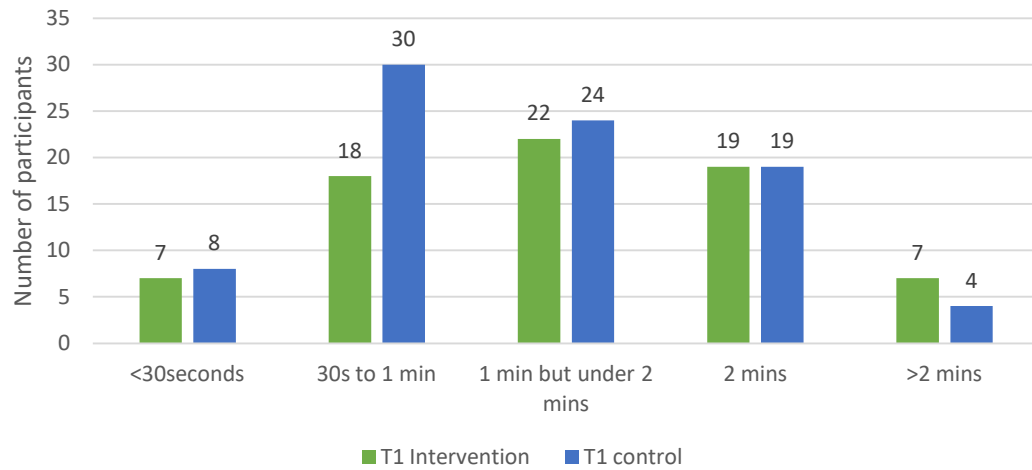
10. Please circle the answer you think most nearly applies to you	Strongly Agree				Strongly Disagree			
a) I think the dental students want me to clean my teeth differently from how I now clean them	1	2	3	4	5	6	7	
b) I don't care how the dental students think I should clean my teeth	1	2	3	4	5	6	7	

Appendix 18

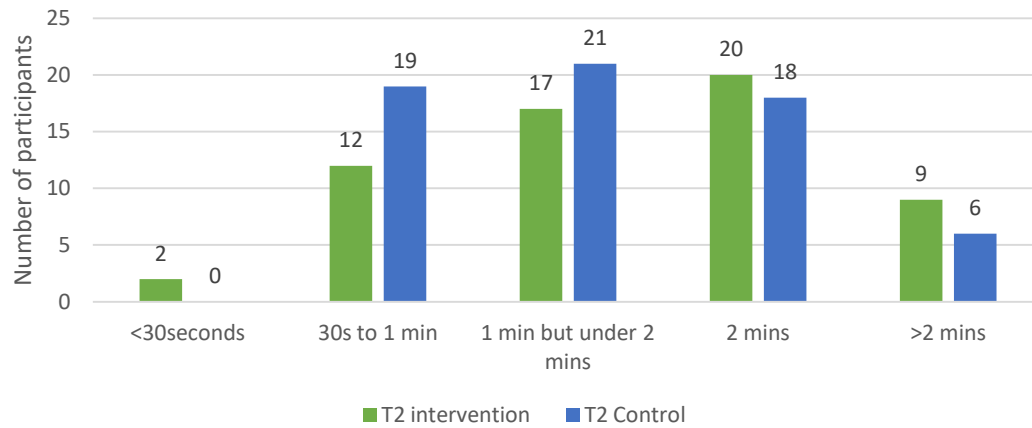
DOOHS Results – Reported Oral Hygiene Behaviours T1, T2 & T3



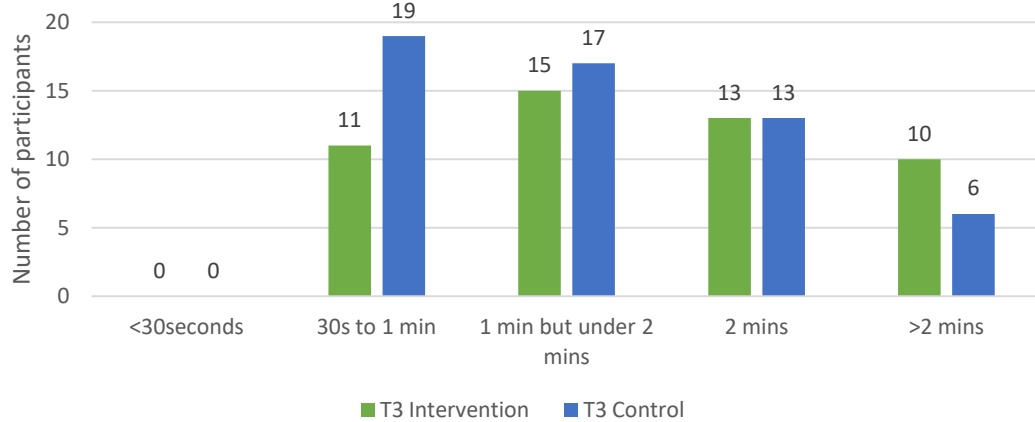
How long do you spend brushing your teeth?



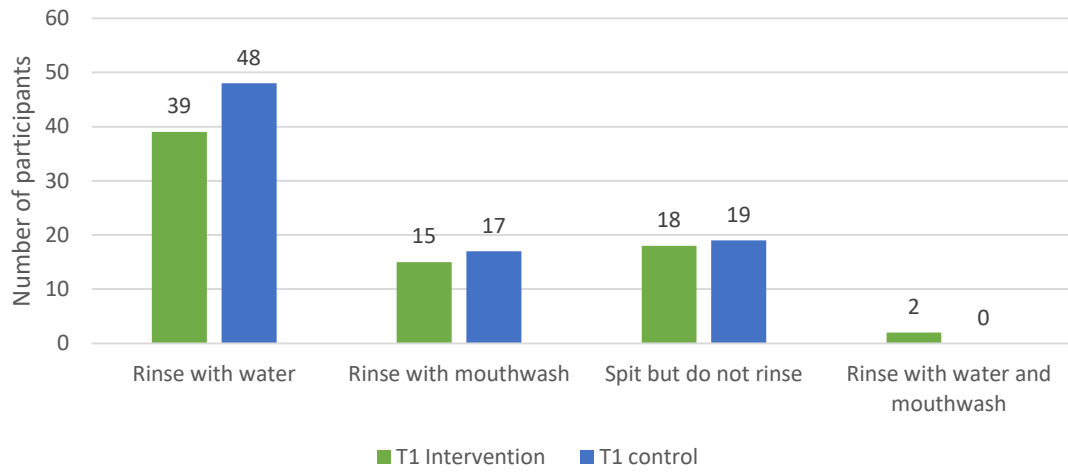
How long do you spend brushing your teeth?



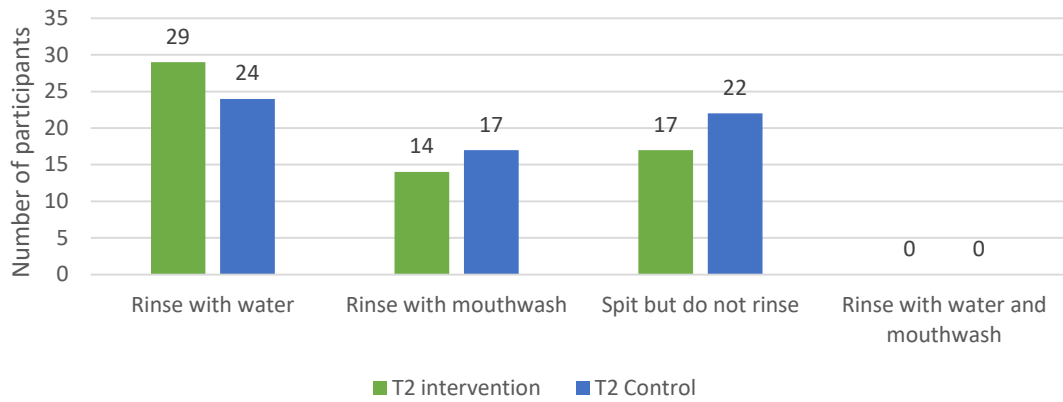
How long do you spend brushing your teeth?



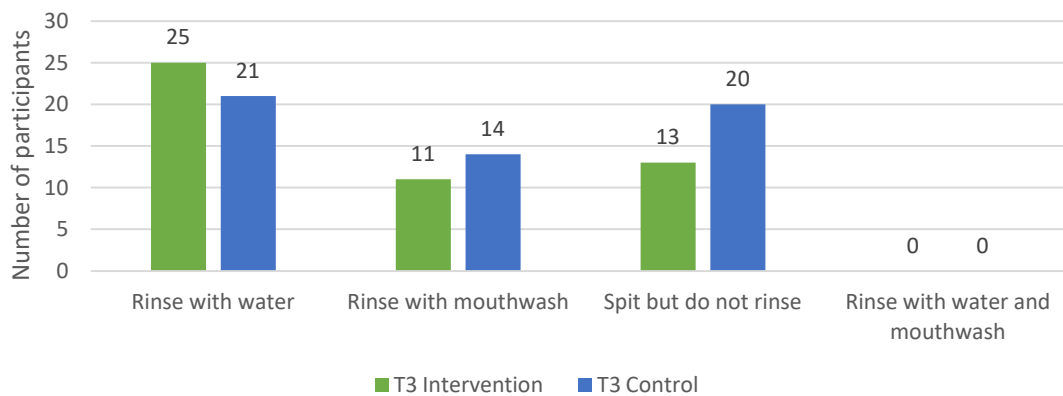
After brushing do you rinse out?



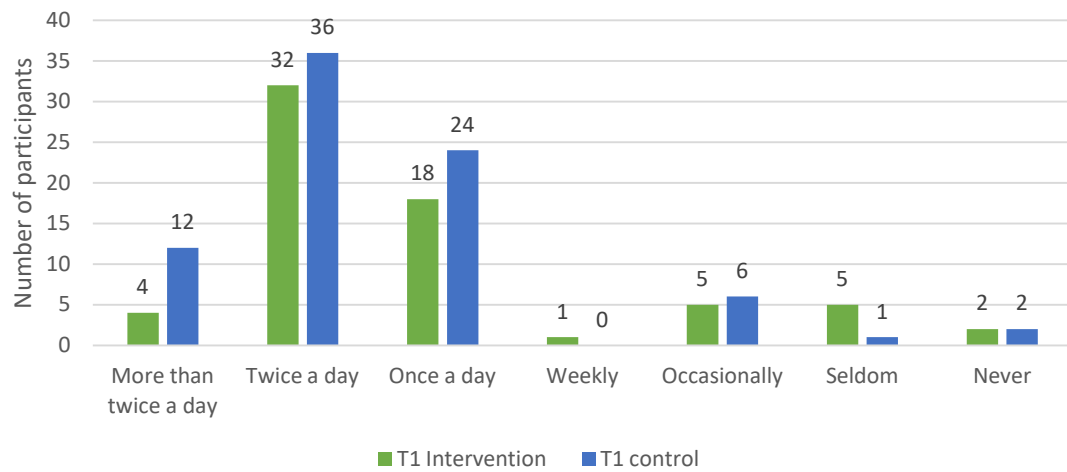
After brushing do you rinse out?



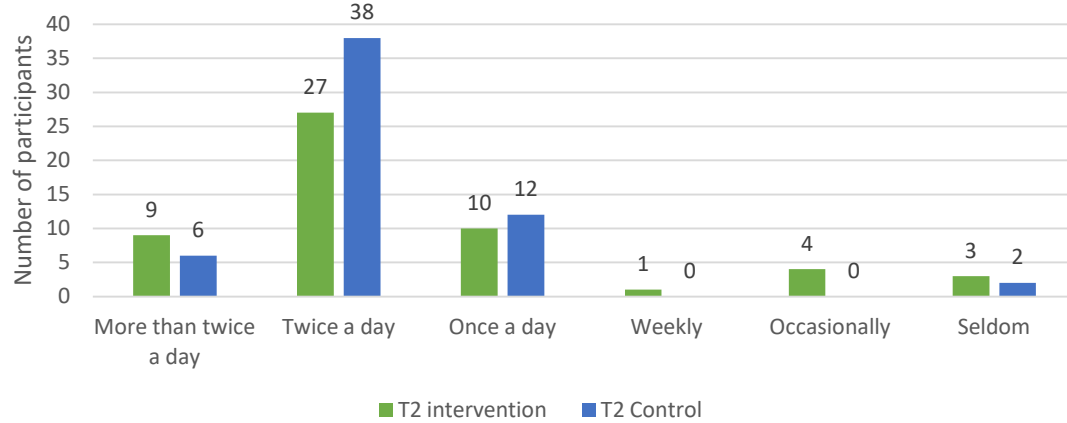
After brushing do you rinse out?



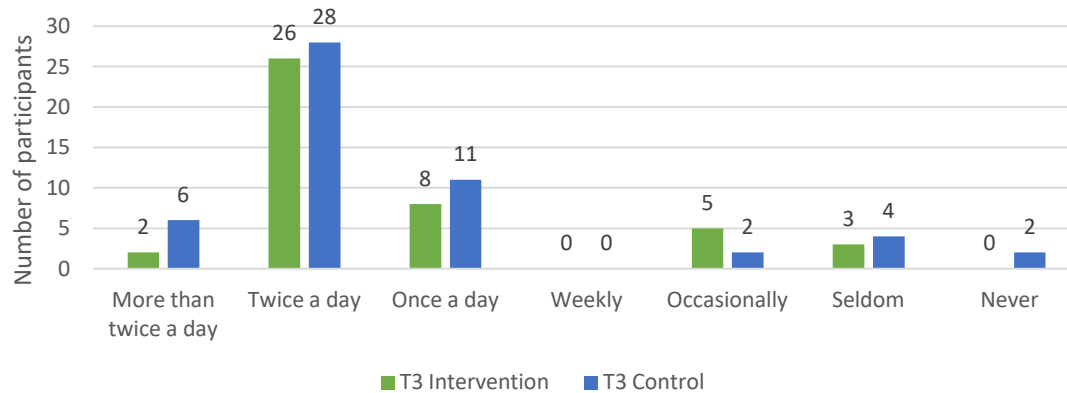
How often do you use a manual toothbrush?



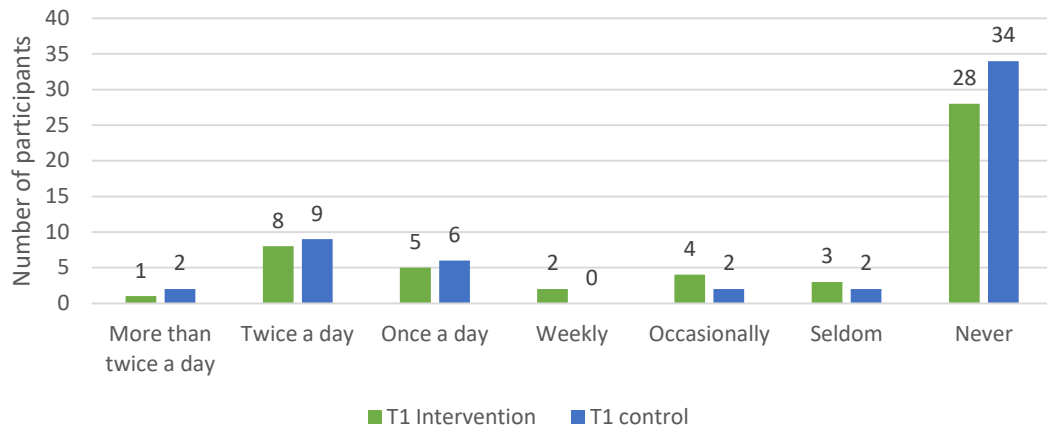
How often do you use a manual toothbrush?



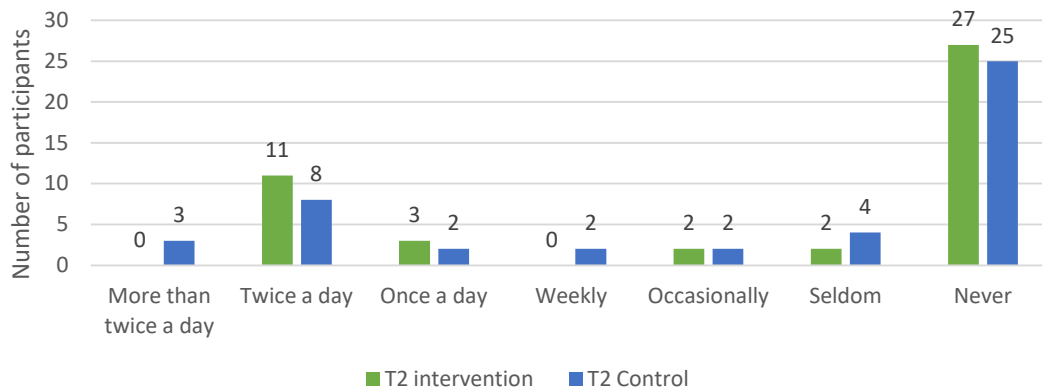
How often do you use a manual toothbrush?



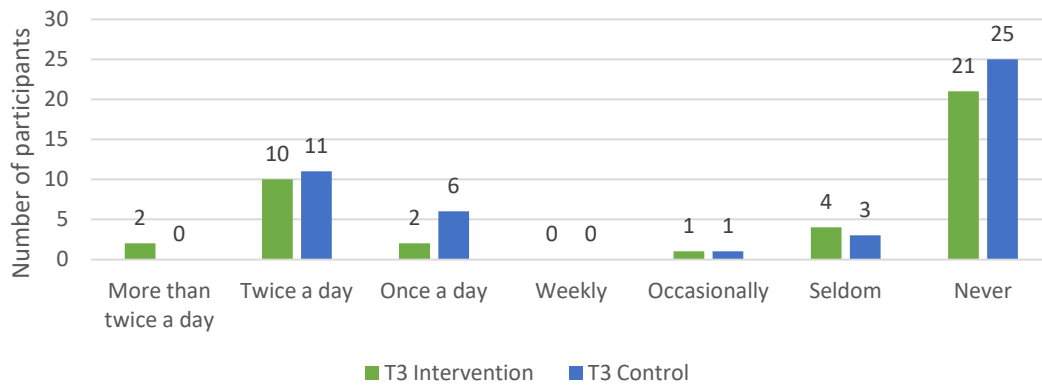
How often do you use an electric toothbrush?



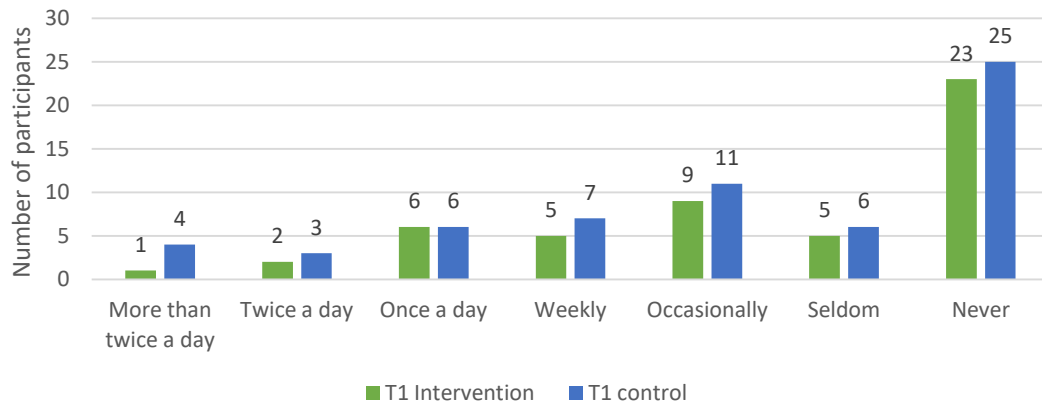
How often do you use an electric toothbrush?



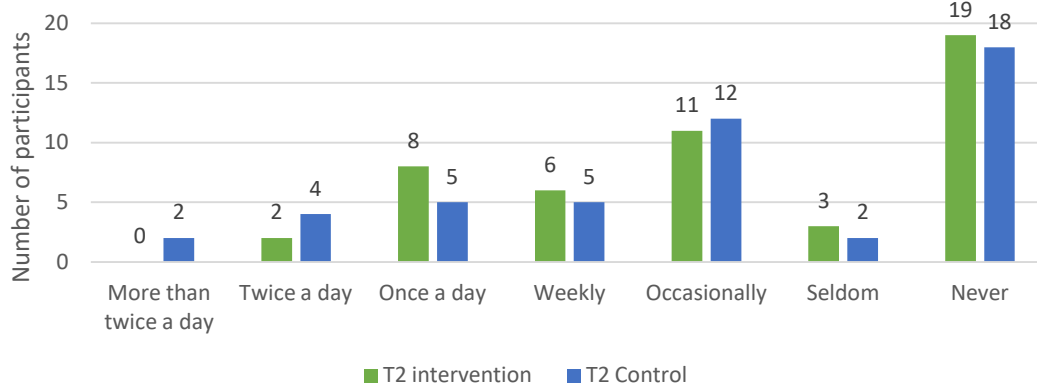
How often do you use an electric toothbrush?



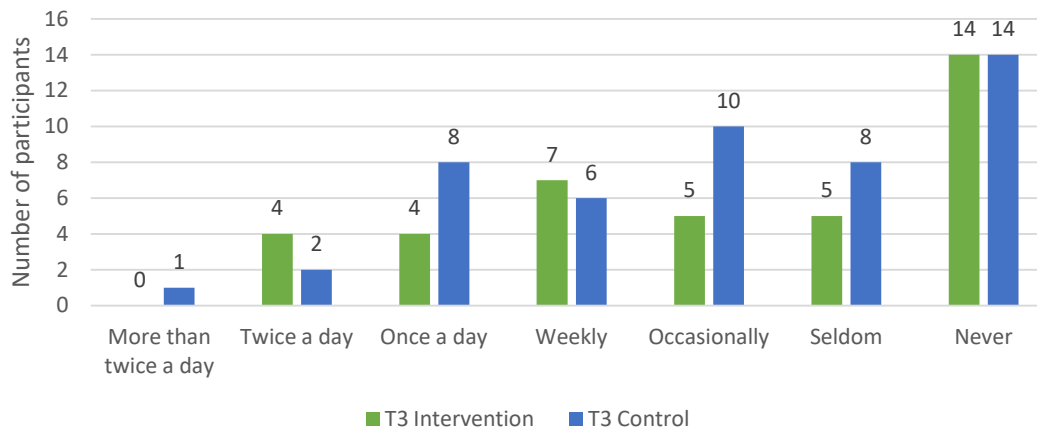
How often do you floss?



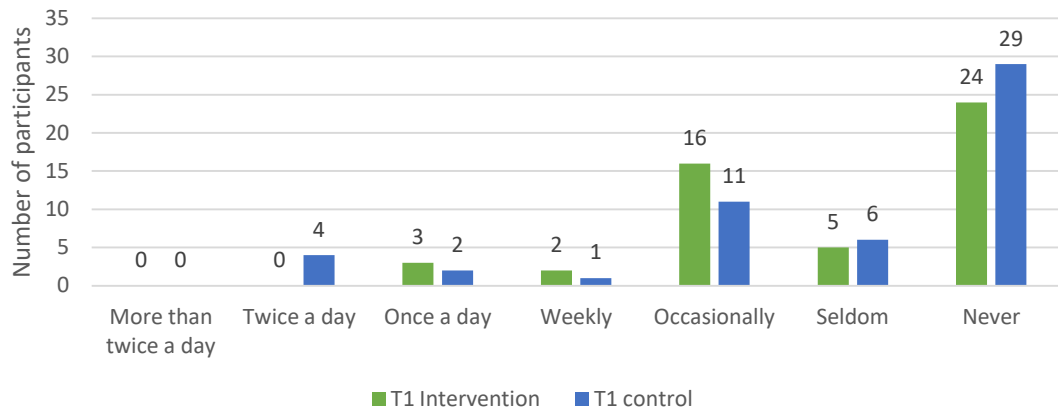
How often do you floss?



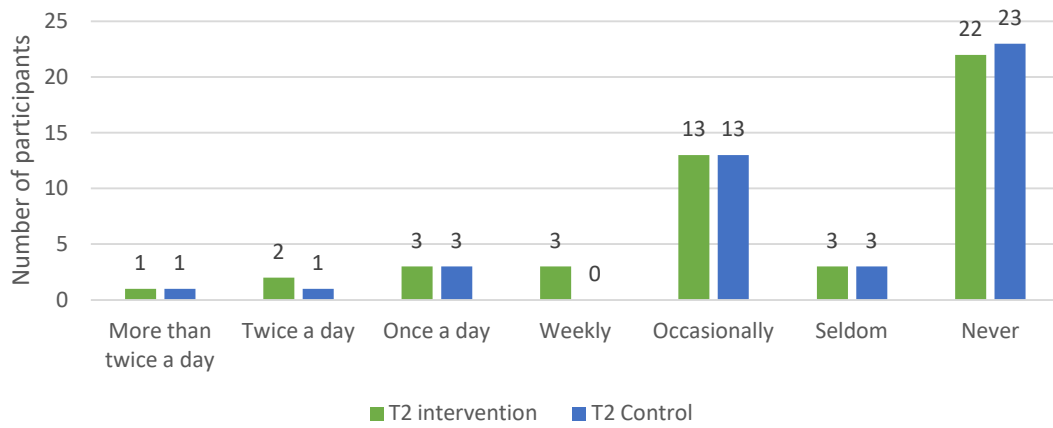
How often do you floss?



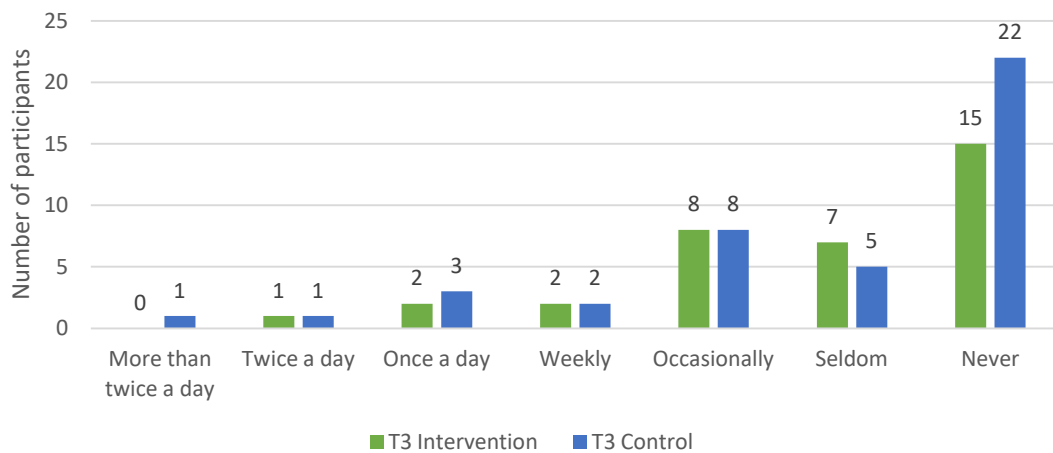
How often do you use toothpicks?



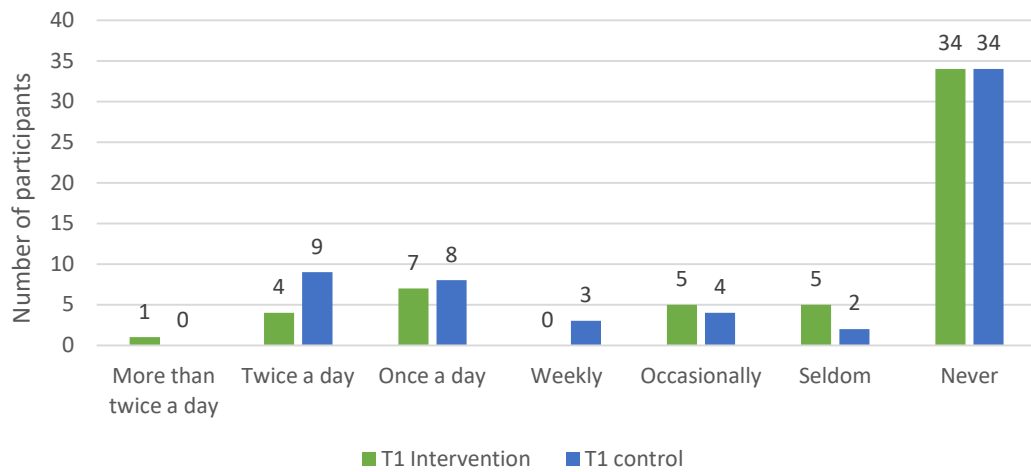
How often do you use toothpicks?



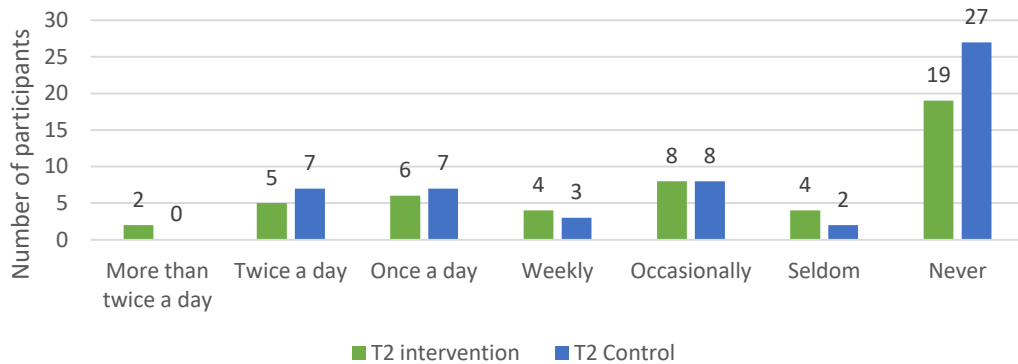
How often do you use toothpicks?



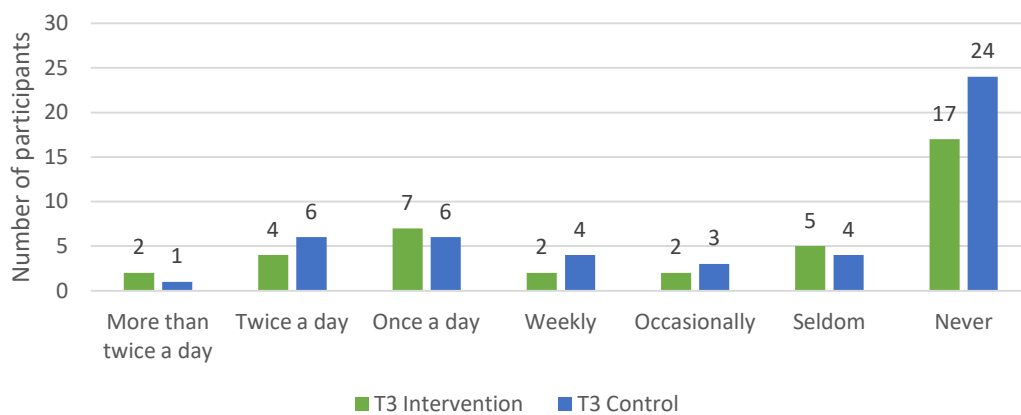
How often do you use brushes between your teeth?



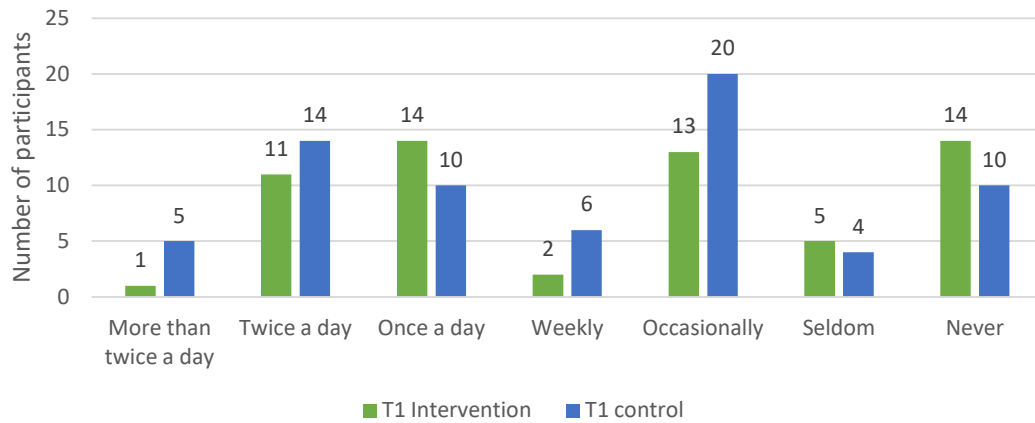
How often do you use brushes between your teeth?



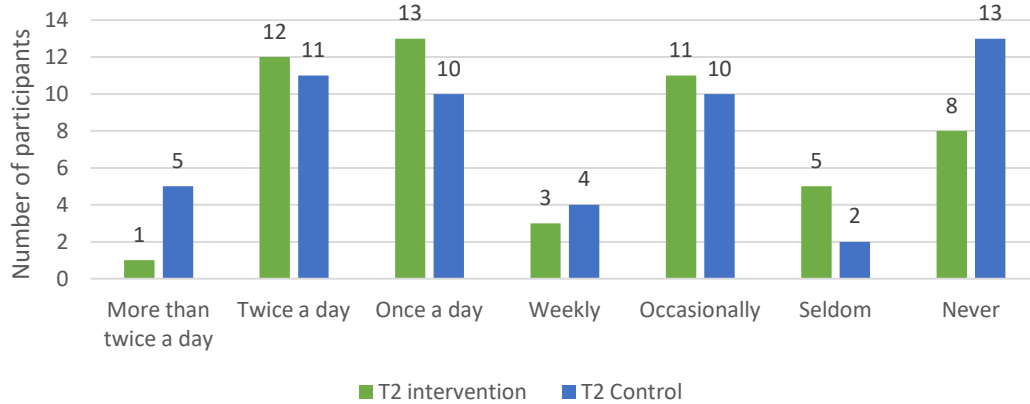
How often do you use brushes between your teeth?



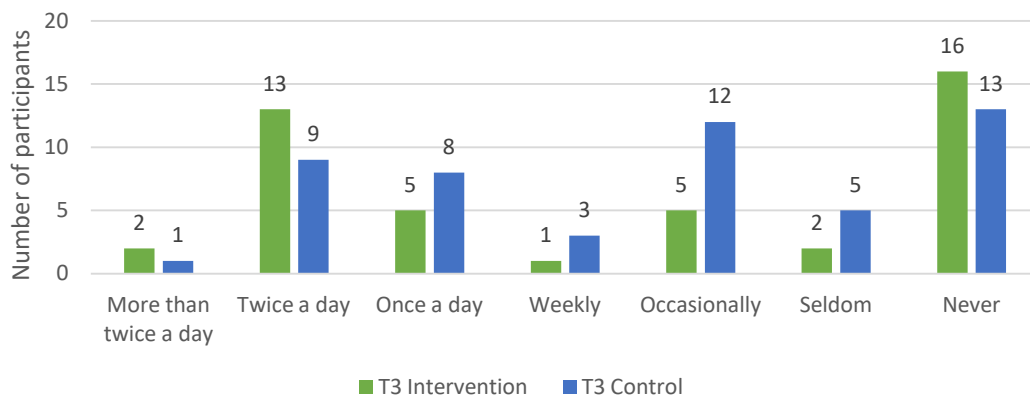
How often do you use mouthwash?



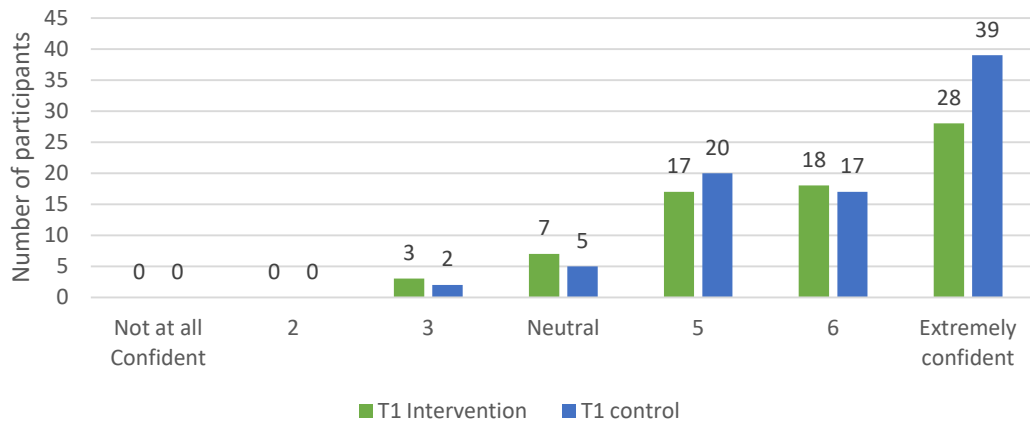
How often do you use mouthwash?



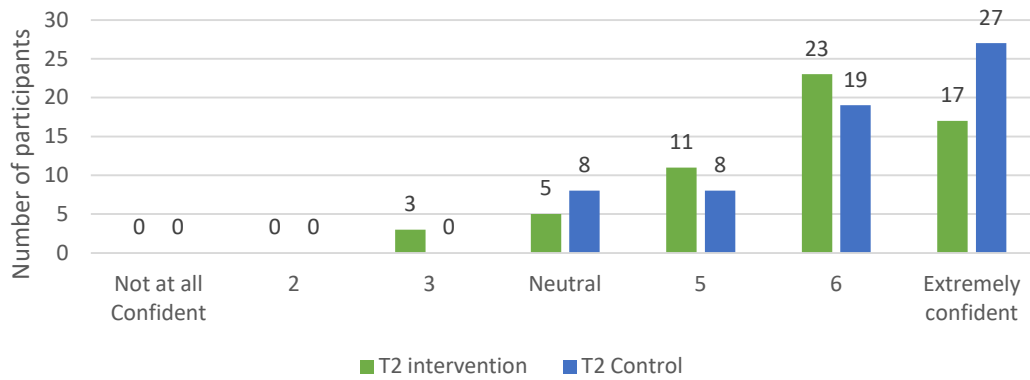
How often do you use mouthwash?



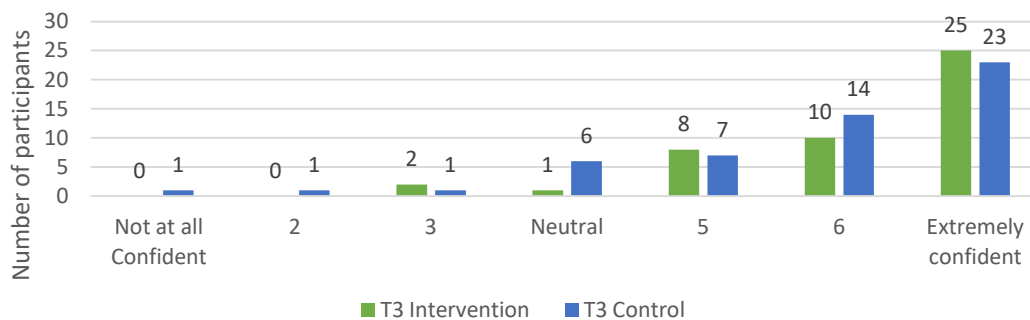
How confident are you that you can follow dental student advice about cleaning your teeth?



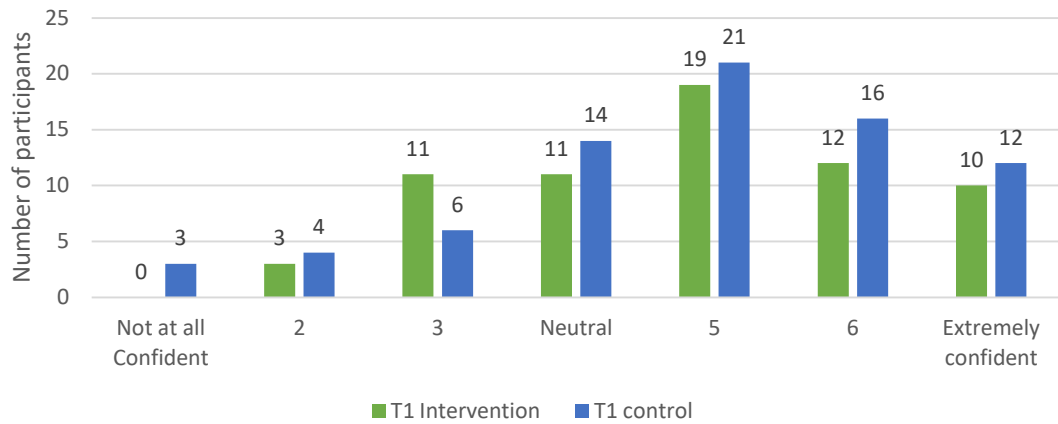
How confident are you that you can follow dental student advice about cleaning your teeth?



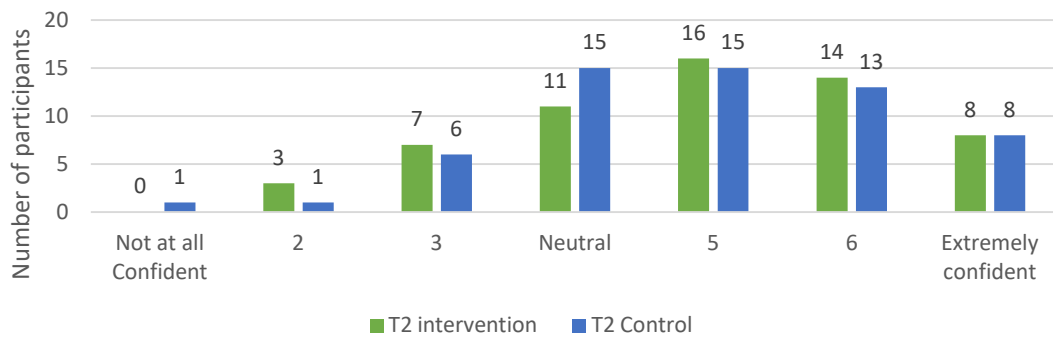
How confident are you that you can follow dental student advice about cleaning your teeth?



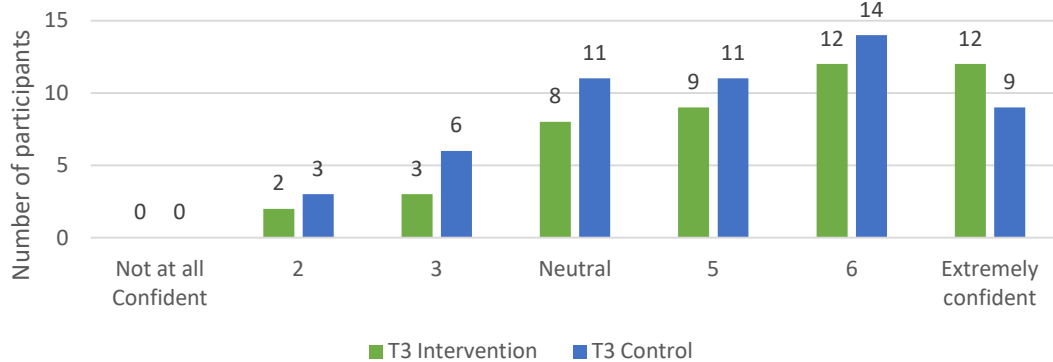
How confident are you that you can clean your teeth so they can't be any cleaner?



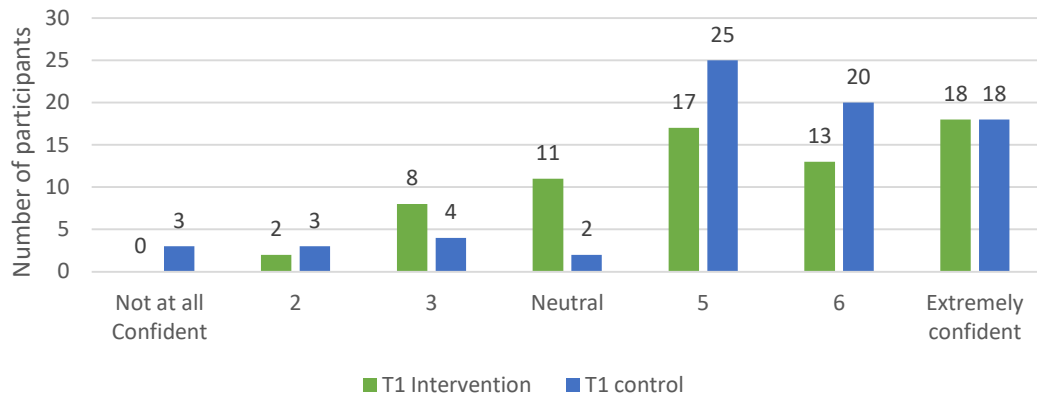
How confident are you that you can clean your teeth so they can't be any cleaner?



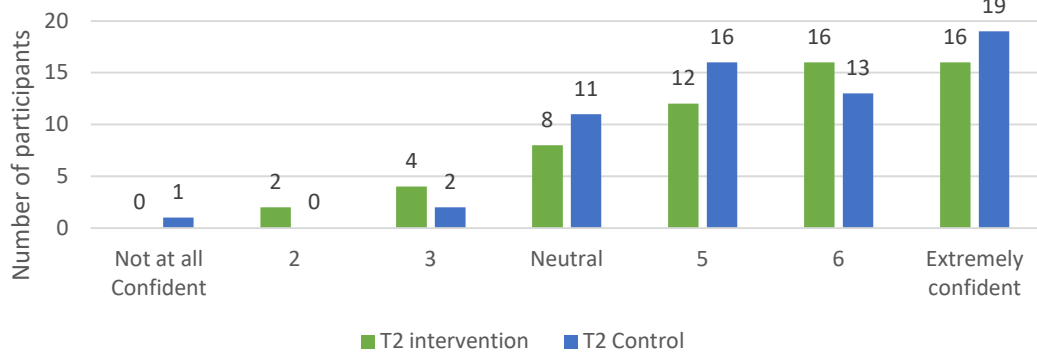
How confident are you that you can clean your teeth so they can't be any cleaner?



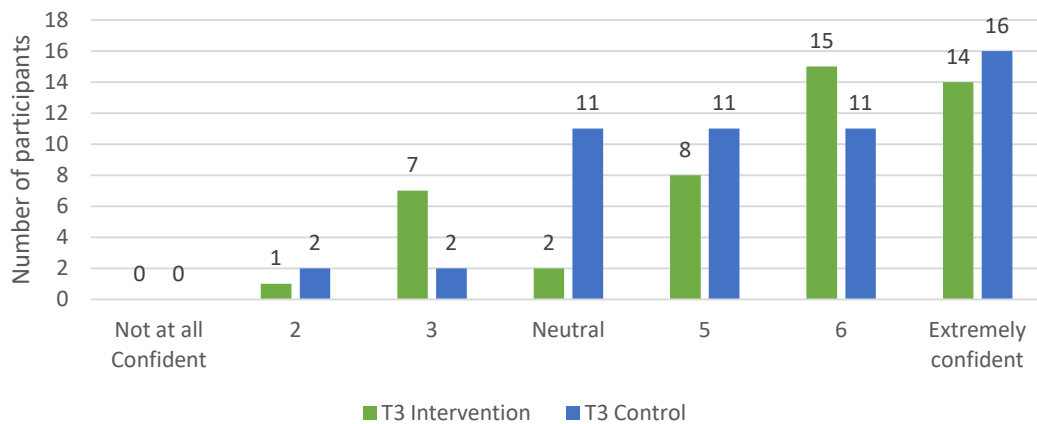
How confident are you that you can clean your teeth as often as you should?



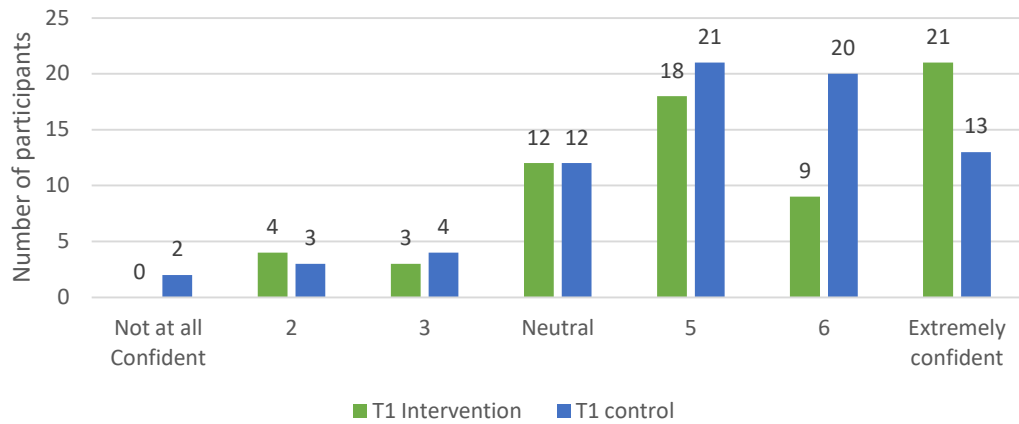
How confident are you that you can clean your teeth as often as you should?



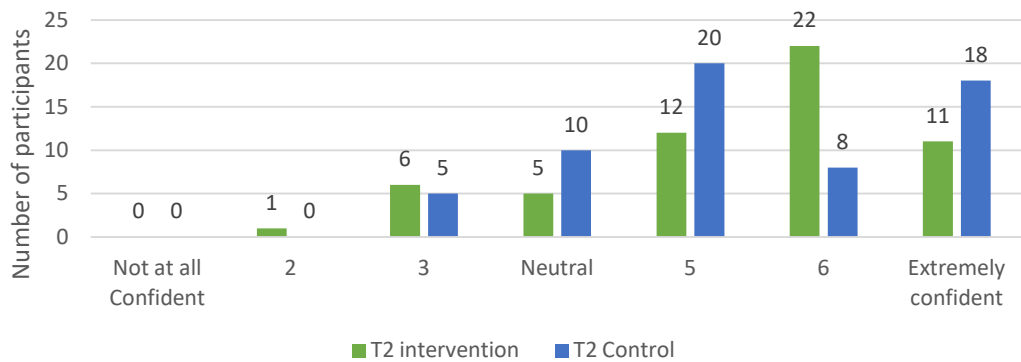
How confident are you that you can clean your teeth as often as you should?



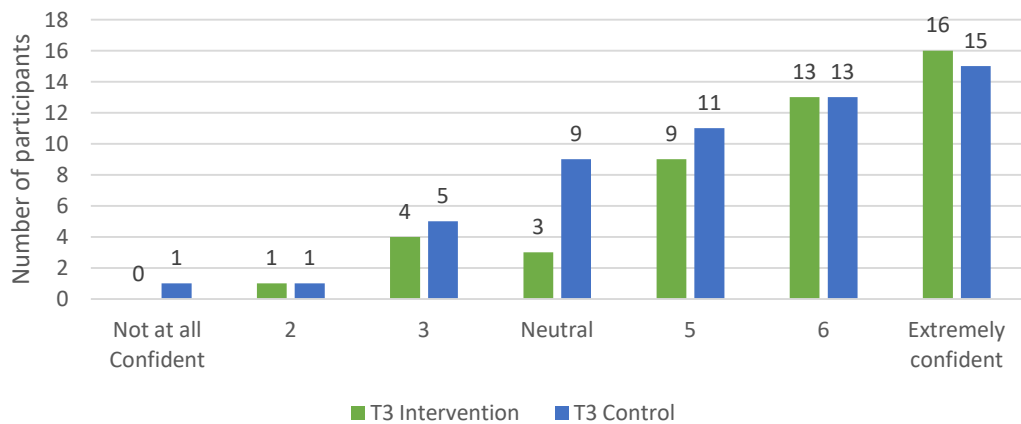
How confident are you that you can clean your teeth for as long as you should?



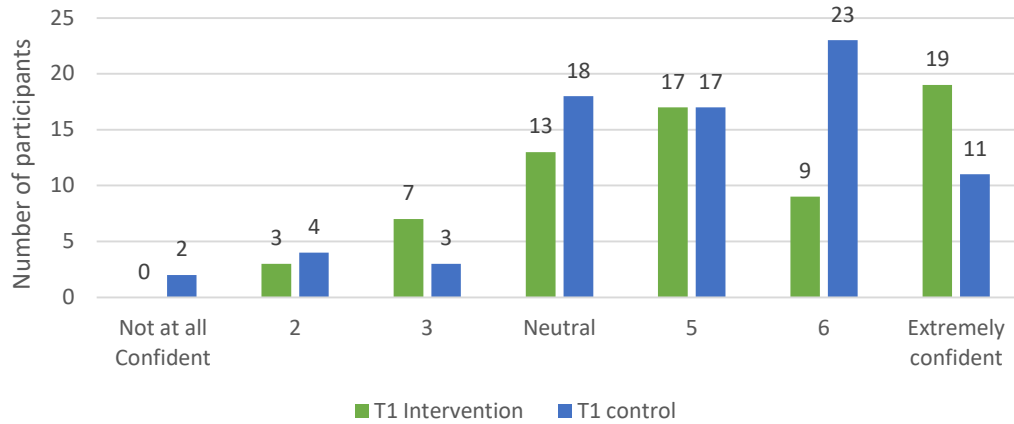
How confident are you that you can clean your teeth for as long as you should?



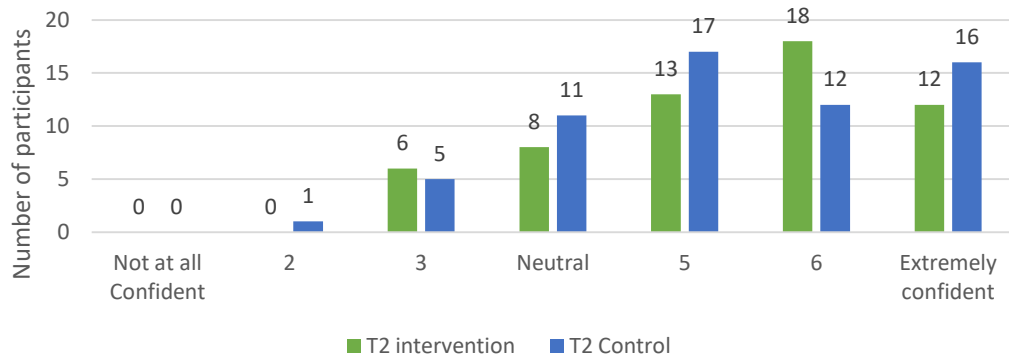
How confident are you that you can clean your teeth for as long as you should?



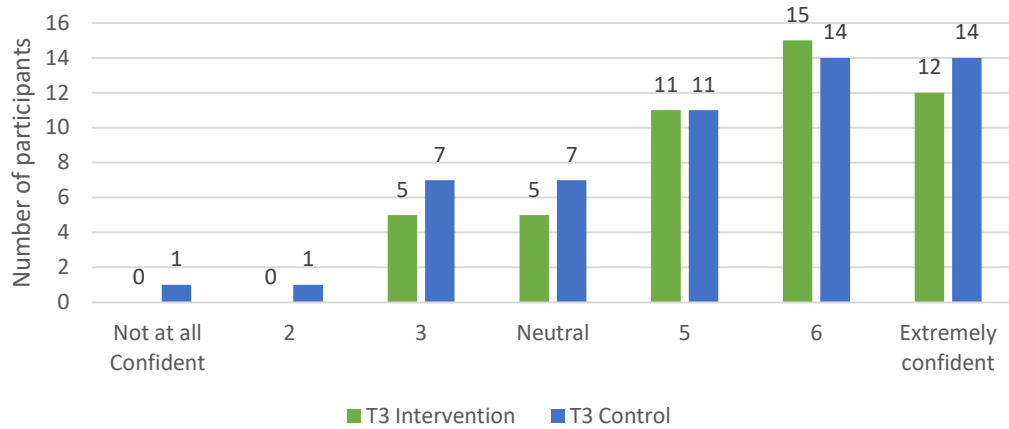
How confident are you that you can clean your teeth the way that you should?



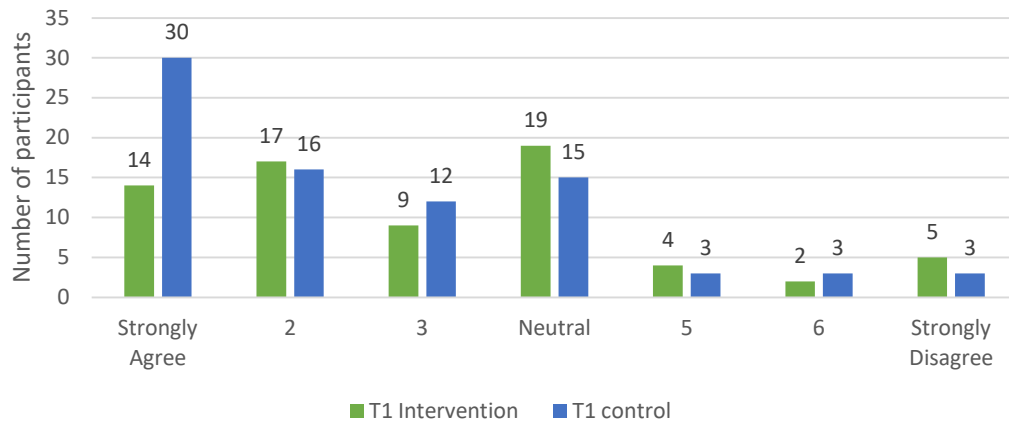
How confident are you that you can clean your teeth the way that you should?



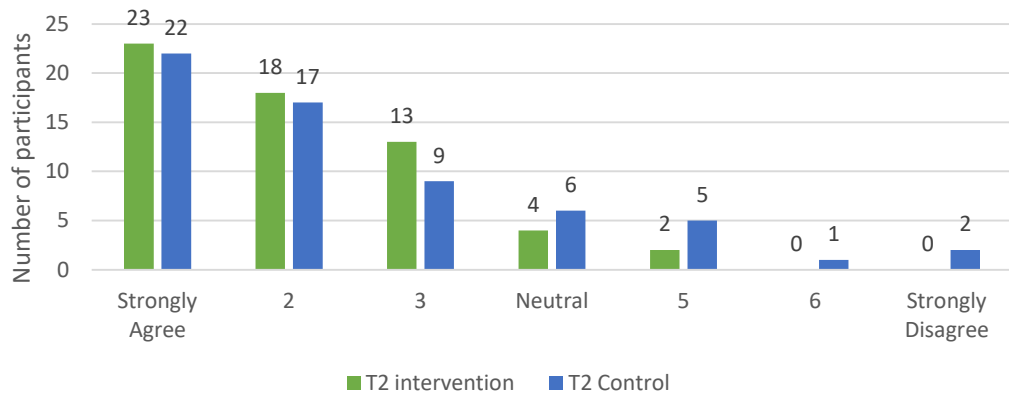
How confident are you that you can clean your teeth the way that you should?



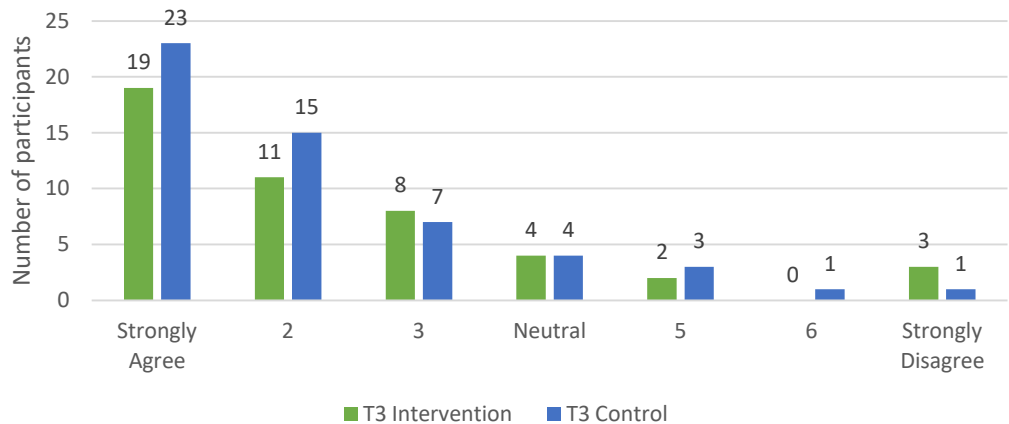
I always find it easy to follow advice from the students about cleaning my teeth



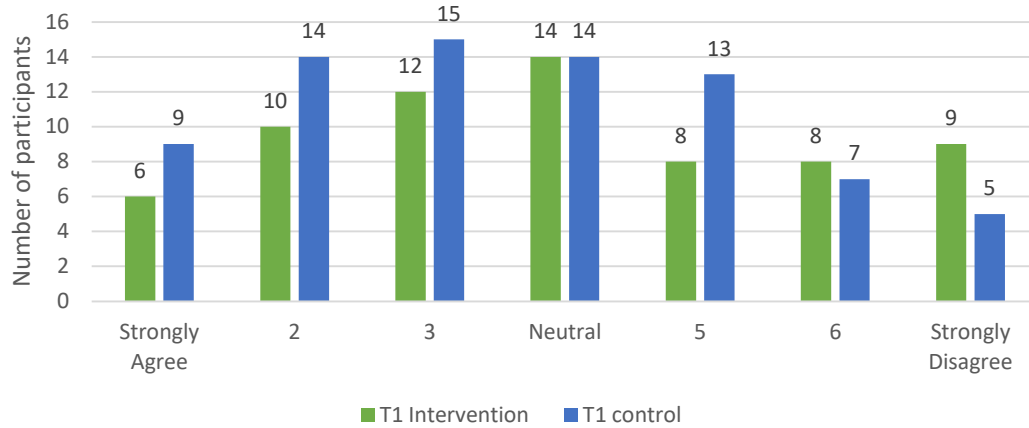
I always find it easy to follow advice from the students about cleaning my teeth



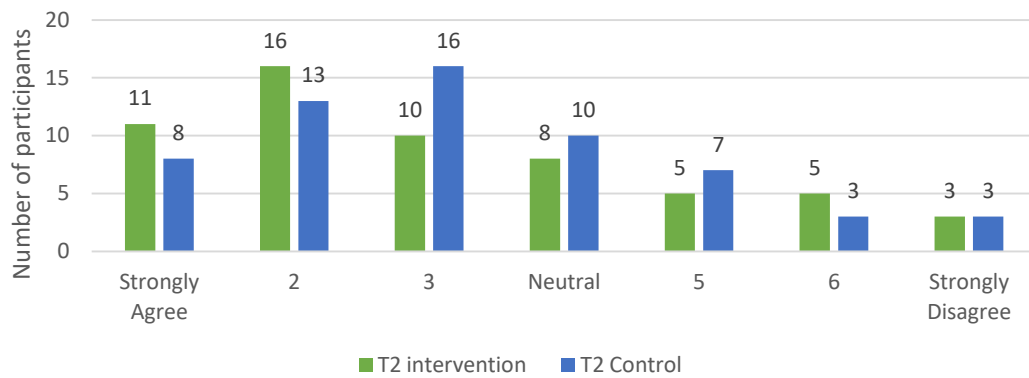
I always find it easy to follow advice from the students about cleaning my teeth



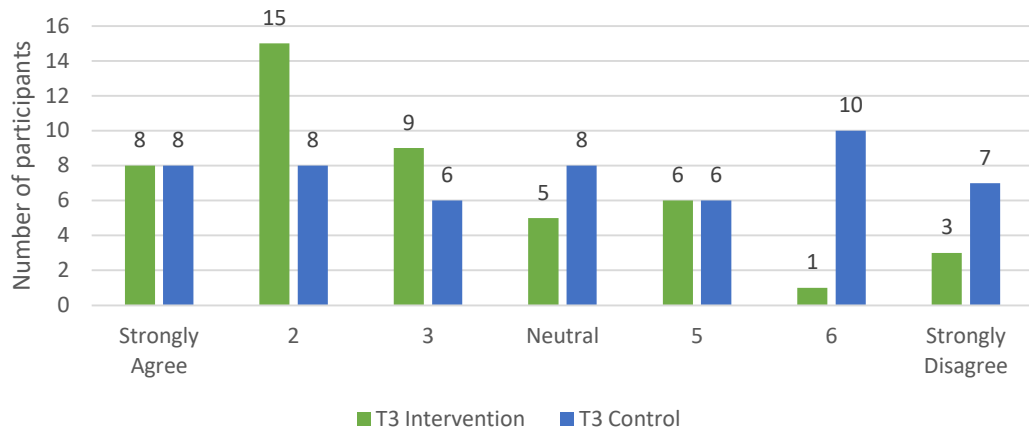
I would always like to clean my teeth until they can't get any cleaner, but I don't think it's possible for me to do so



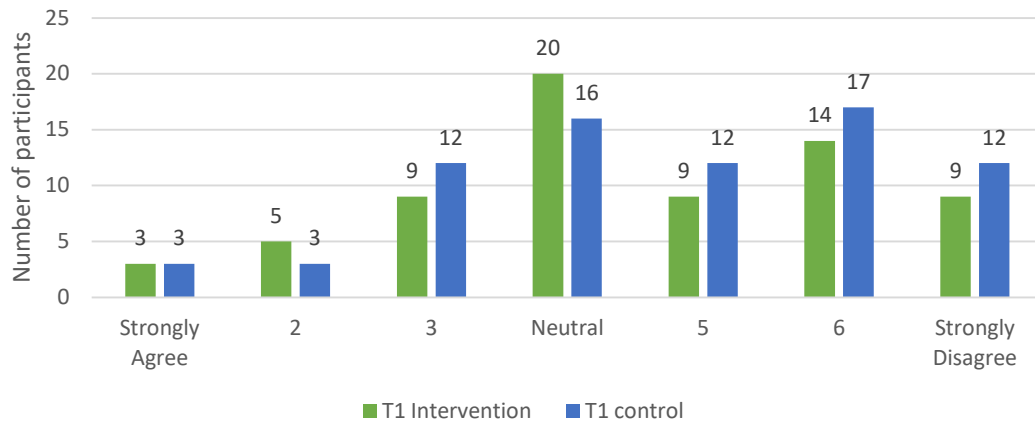
I would always like to clean my teeth until they can't get any cleaner, but I don't think it's possible for me to do so



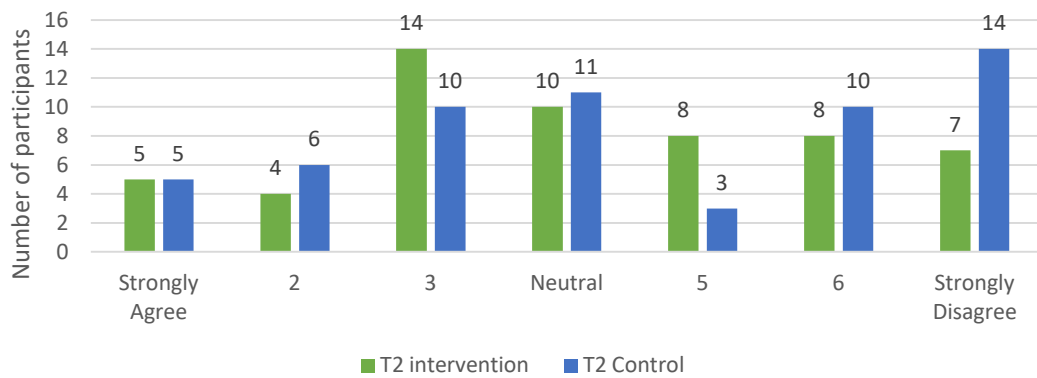
I would always like to clean my teeth until they can't get any cleaner, but I don't think it's possible for me to do so



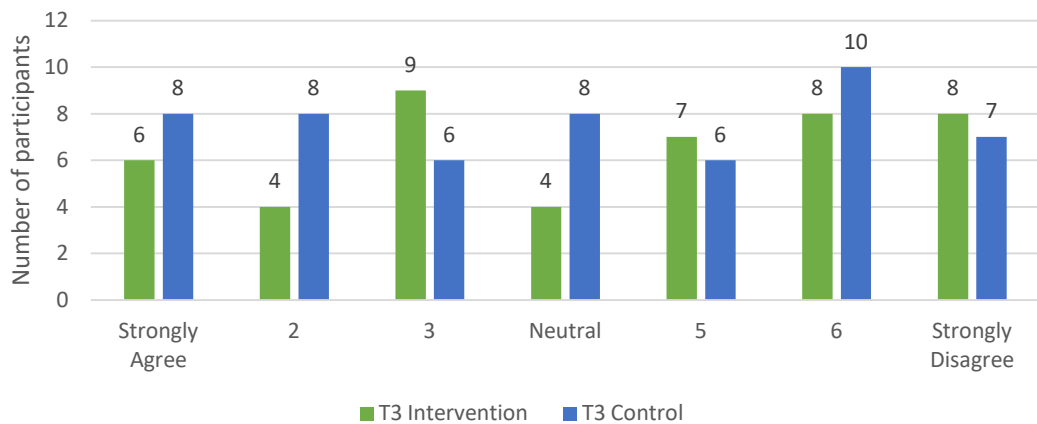
I would like to clean my teeth as often as I should, but I don't think it's possible for me to do so



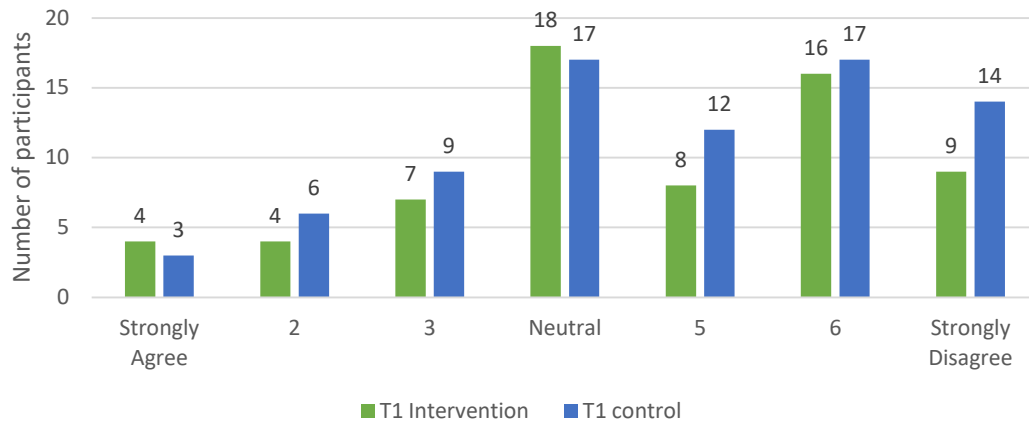
I would like to clean my teeth as often as I should, but I don't think it's possible for me to do so



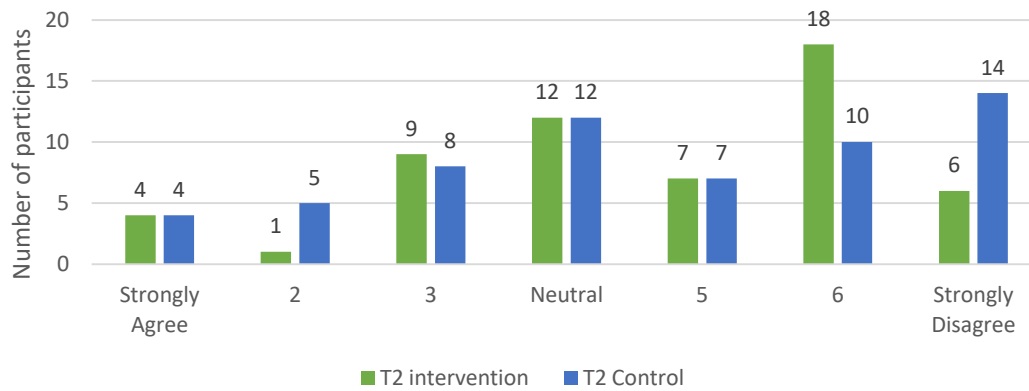
I would like to clean my teeth as often as I should, but I don't think it's possible for me to do so



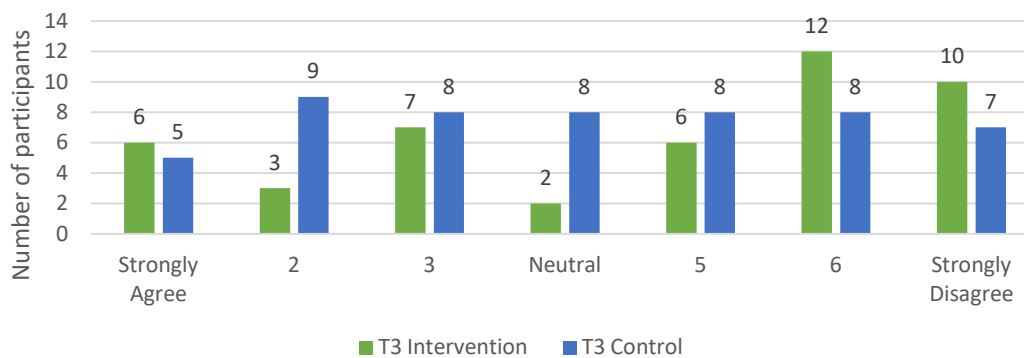
I would like to clean my teeth for as long as I should, but
I don't think it's possible for me to do so



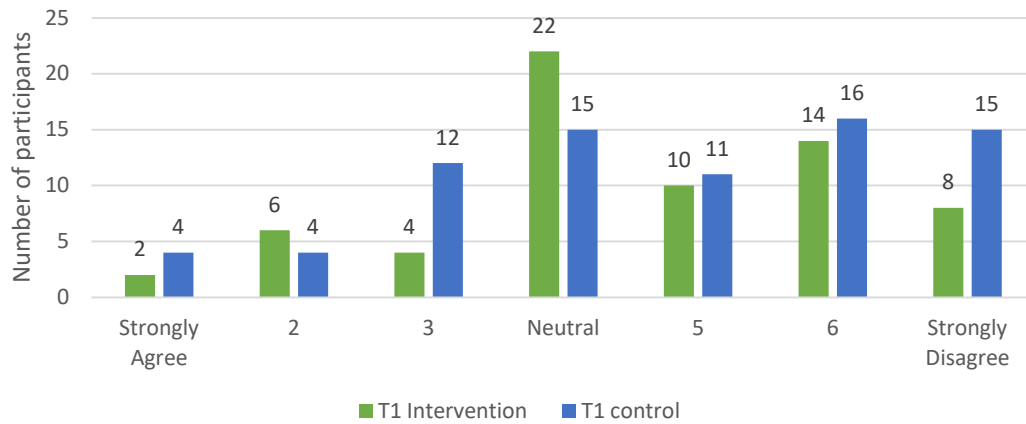
I would like to clean my teeth for as long as I should, but
I don't think it's possible for me to do so



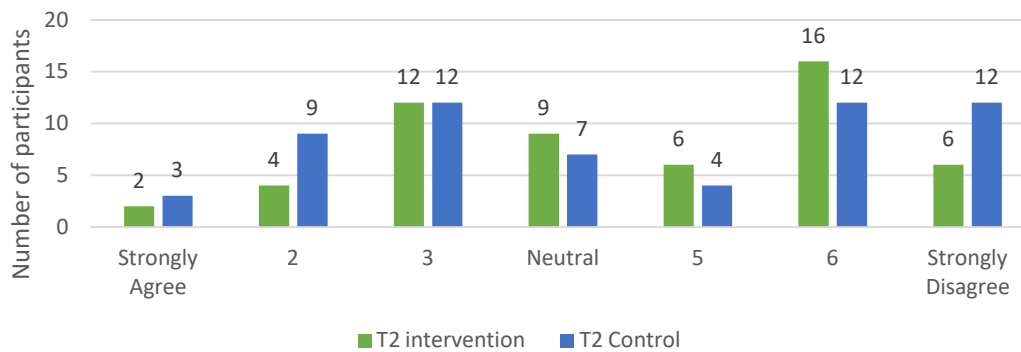
I would like to clean my teeth for as long as I should, but
I don't think it's possible for me to do so



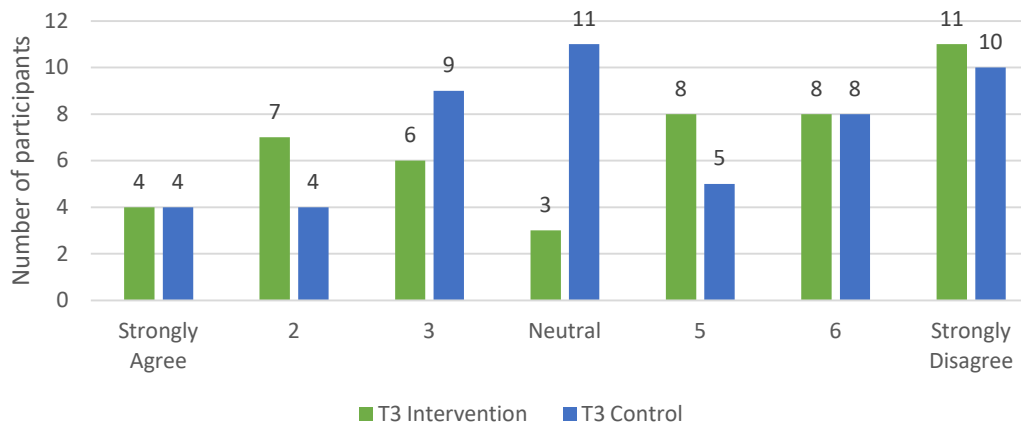
I would like to clean my teeth the way should, but I don't think it's possible for me to do so



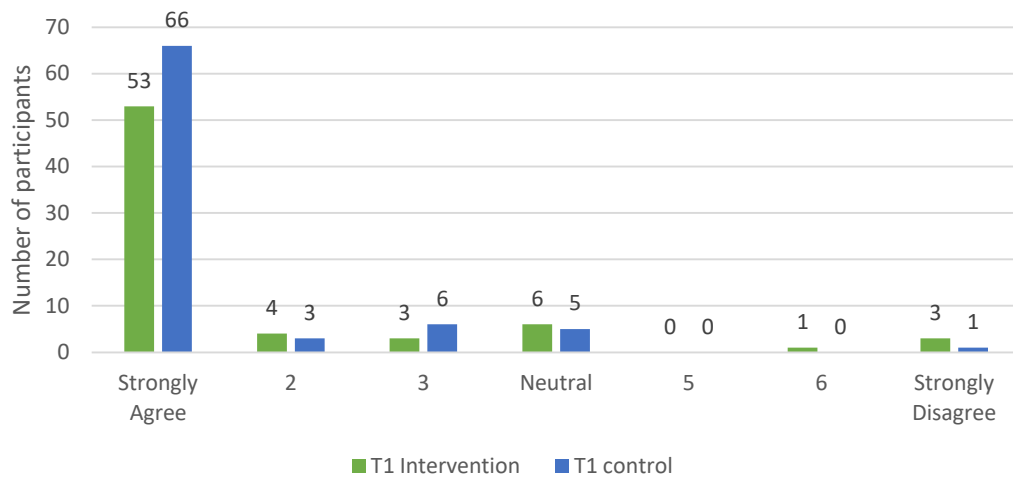
I would like to clean my teeth the way should, but I don't think it's possible for me to do so



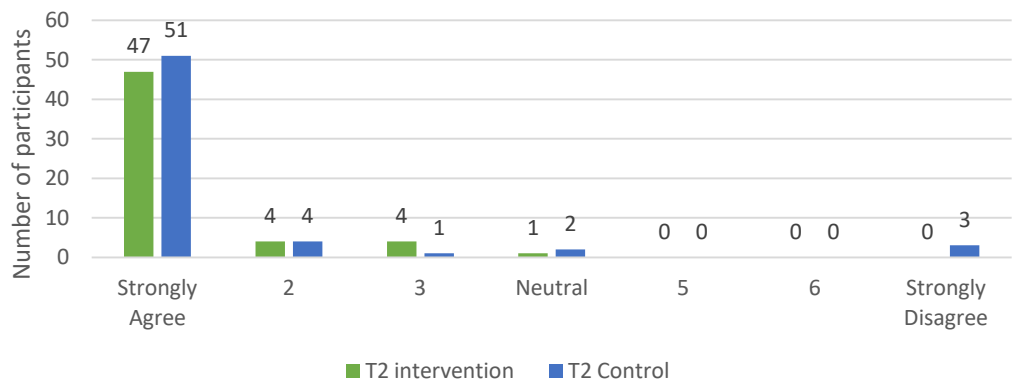
I would like to clean my teeth the way should, but I don't think it's possible for me to do so



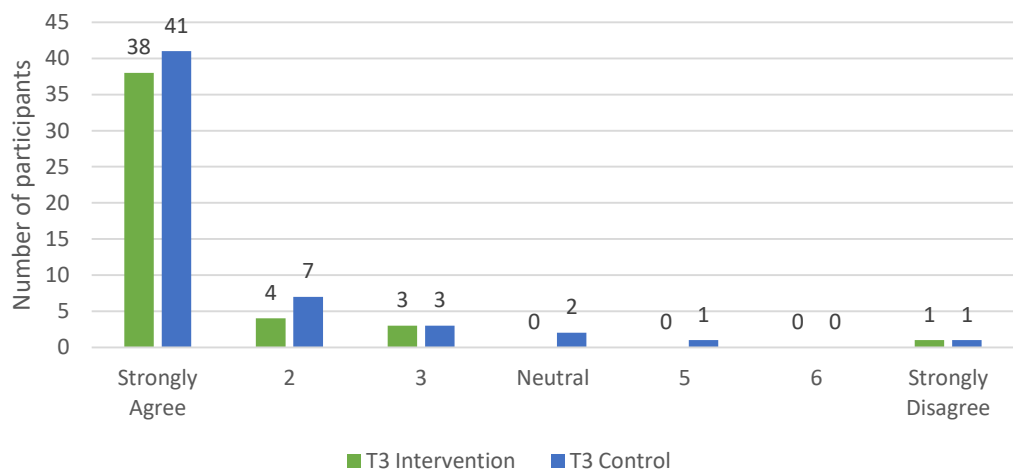
Cleaning my teeth is a good thing to do



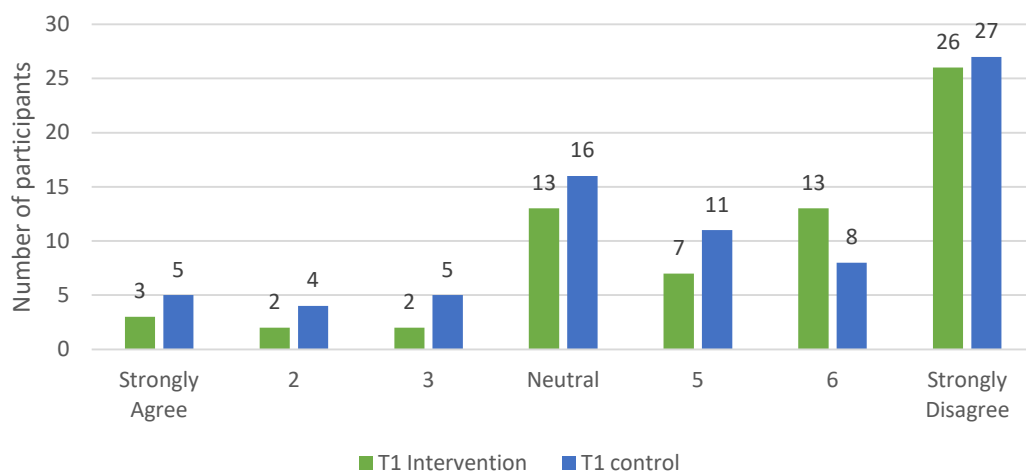
Cleaning my teeth is a good thing to do



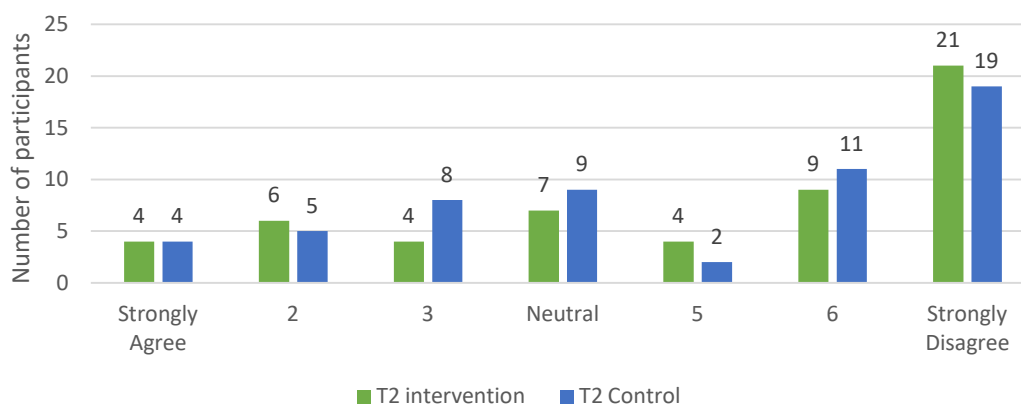
Cleaning my teeth is a good thing to do



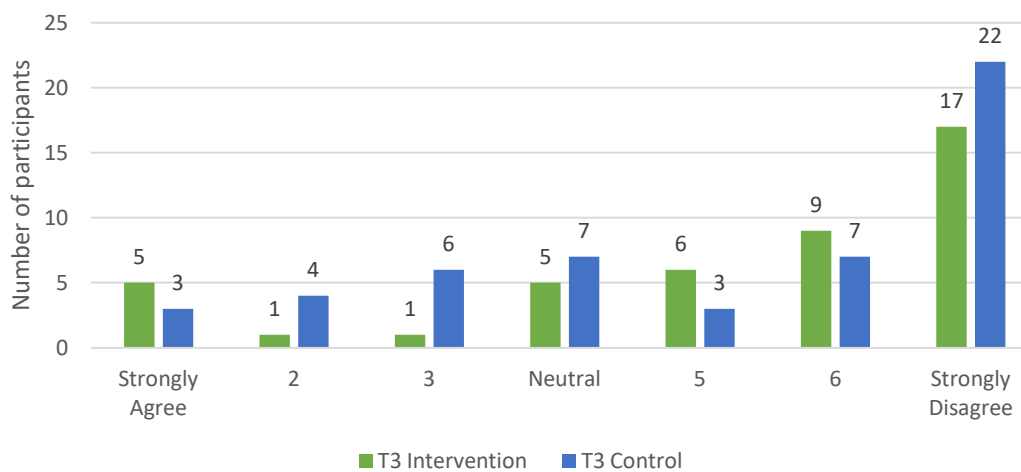
Cleaning my teeth is a boring thing to do



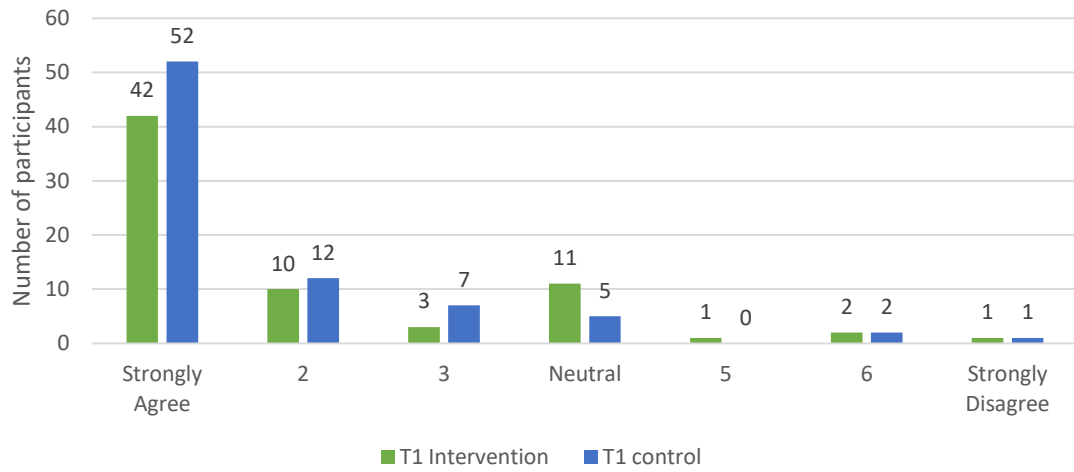
Cleaning my teeth is a boring thing to do



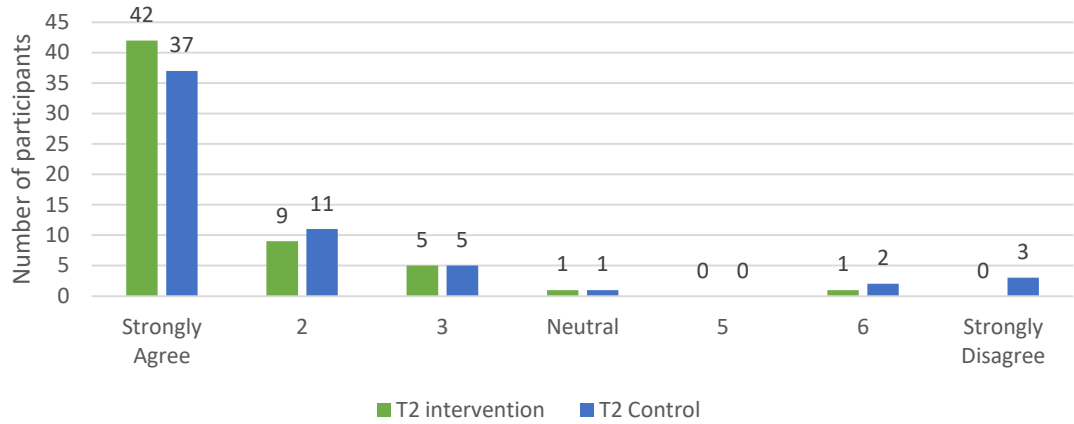
Cleaning my teeth is a boring thing to do



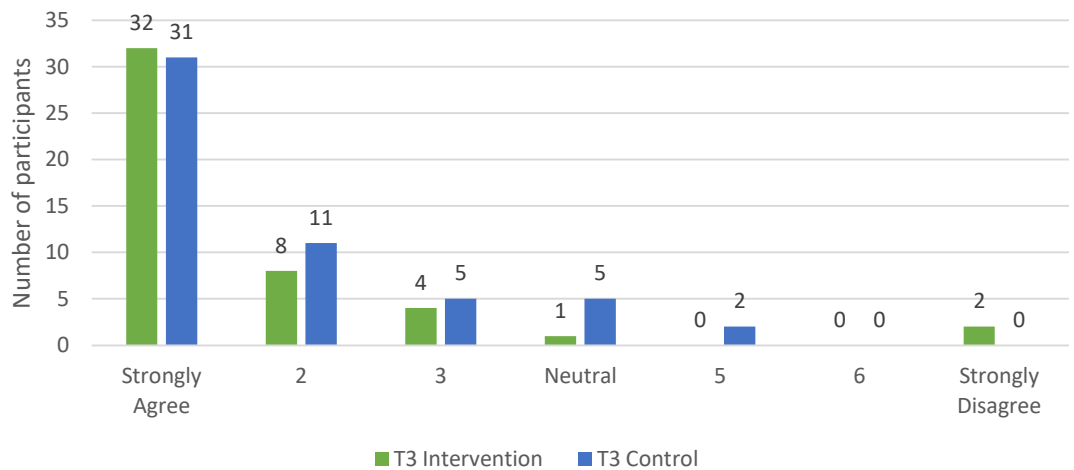
Cleaning my teeth makes my mouth feel good



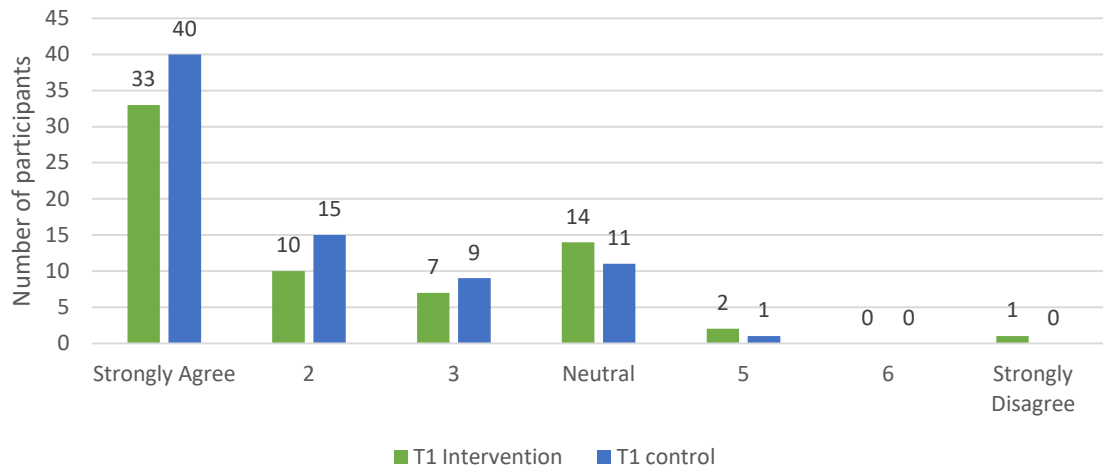
Cleaning my teeth makes my mouth feel good



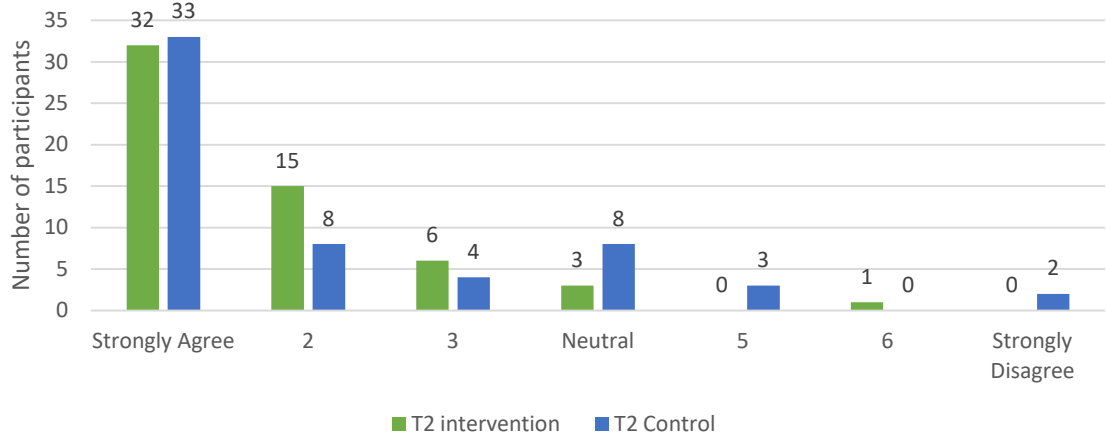
Cleaning my teeth makes my mouth feel good



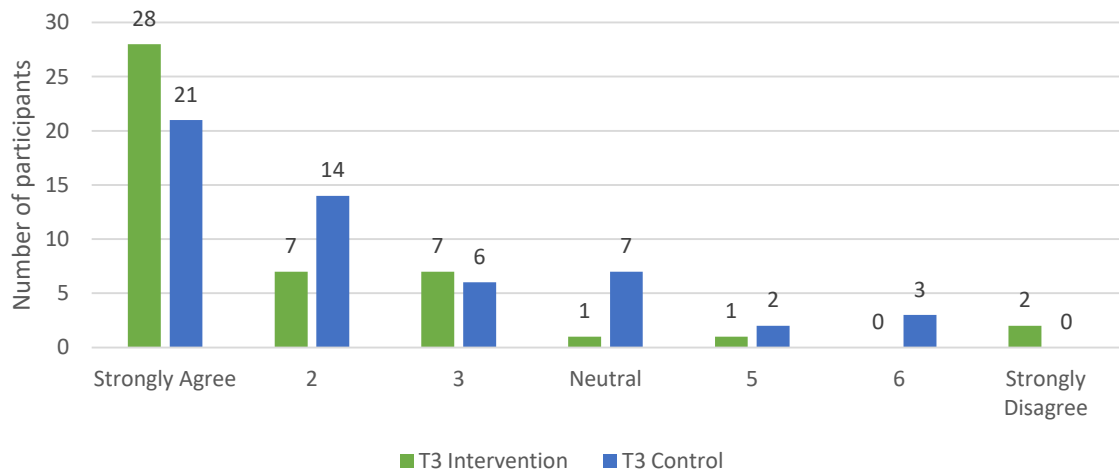
The more I clean my teeth the less decay I will get



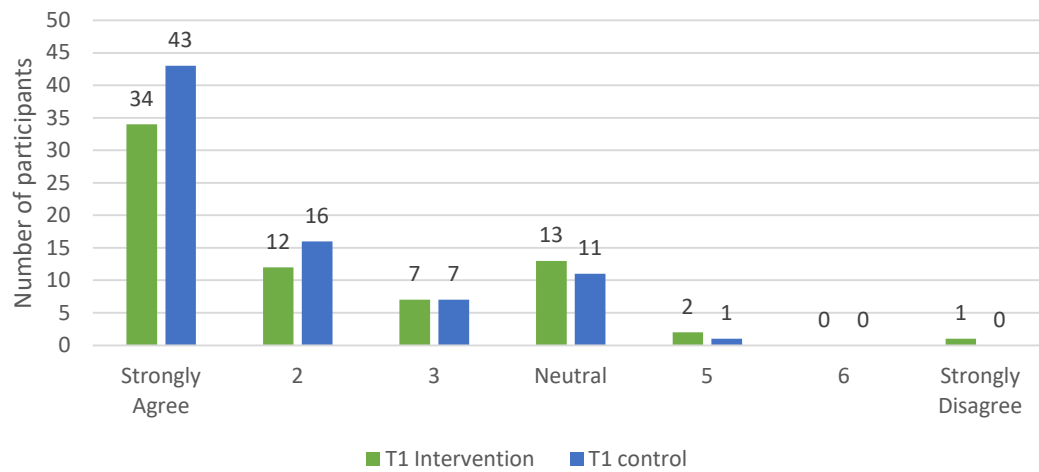
The more I clean my teeth the less decay I will get



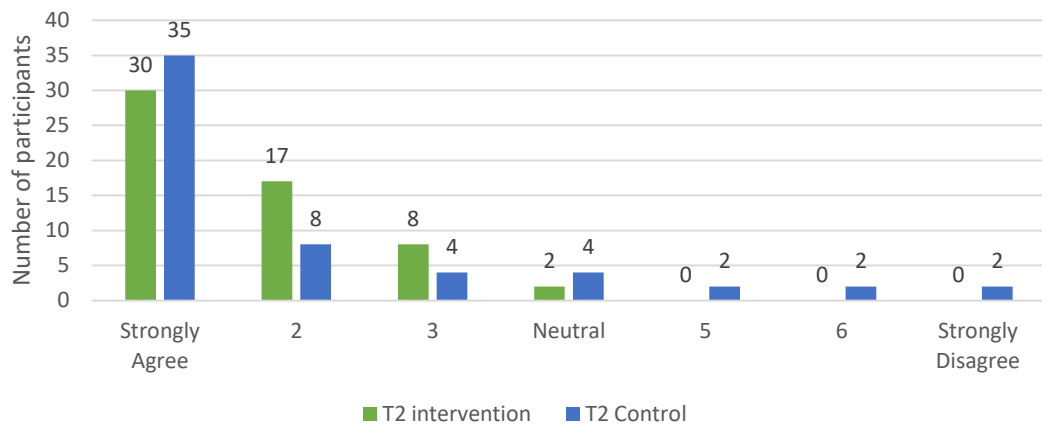
The more I clean my teeth the less decay I will get



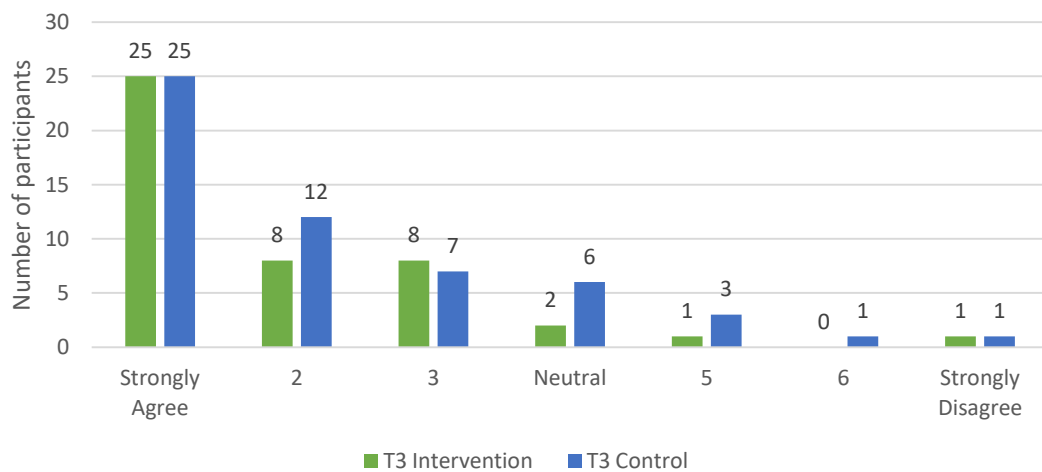
The more I clean my teeth the less gum disease I will get



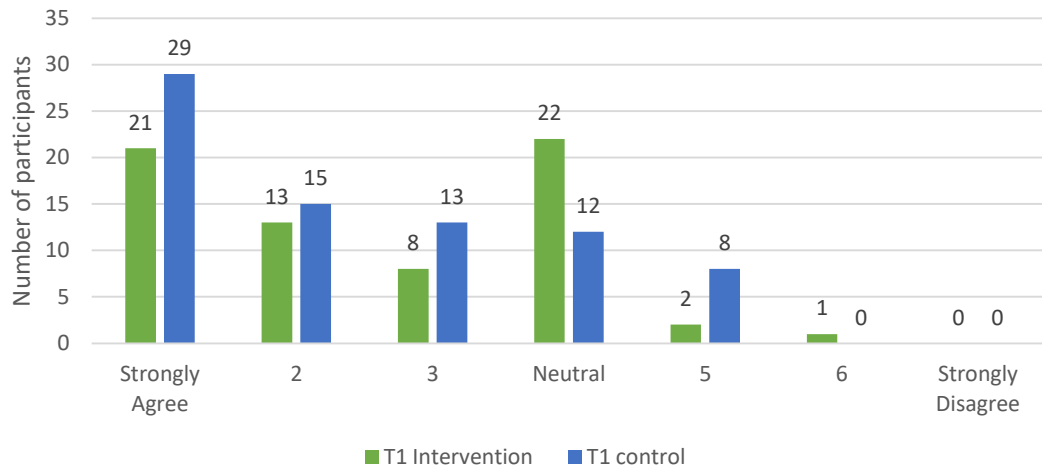
The more I clean my teeth the less gum disease I will get



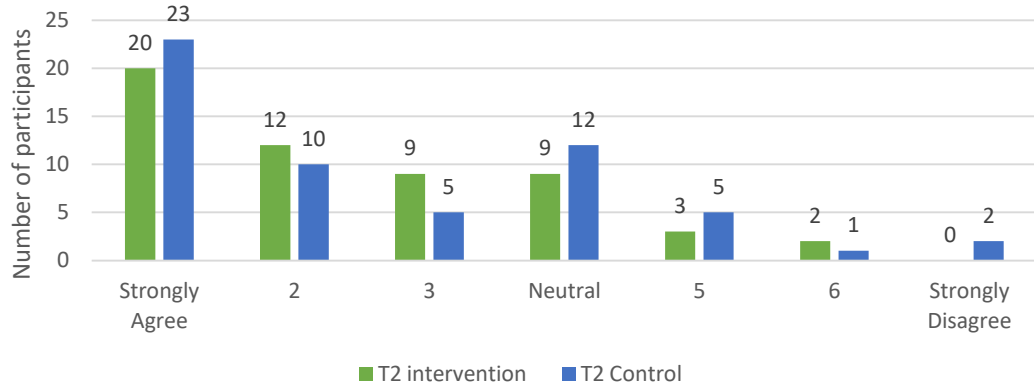
The more I clean my teeth the less gum disease I will get



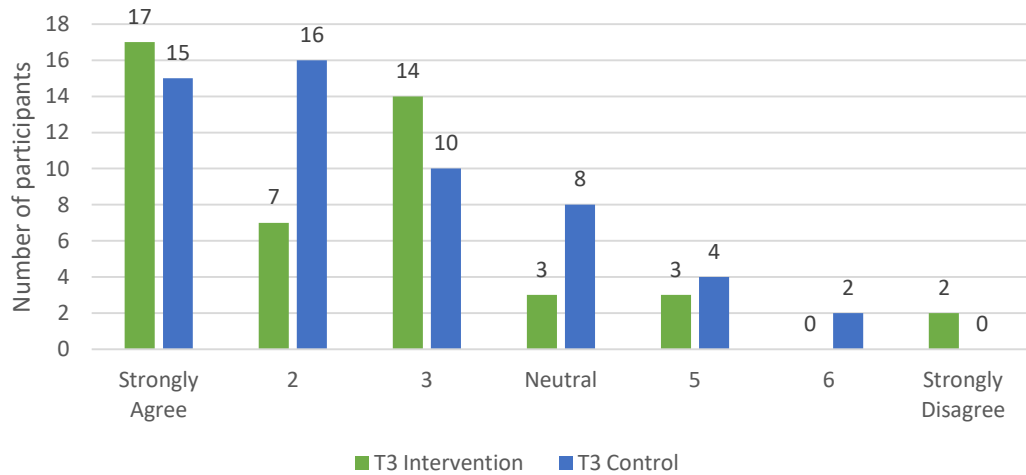
The longer I clean my teeth the less decay I will get



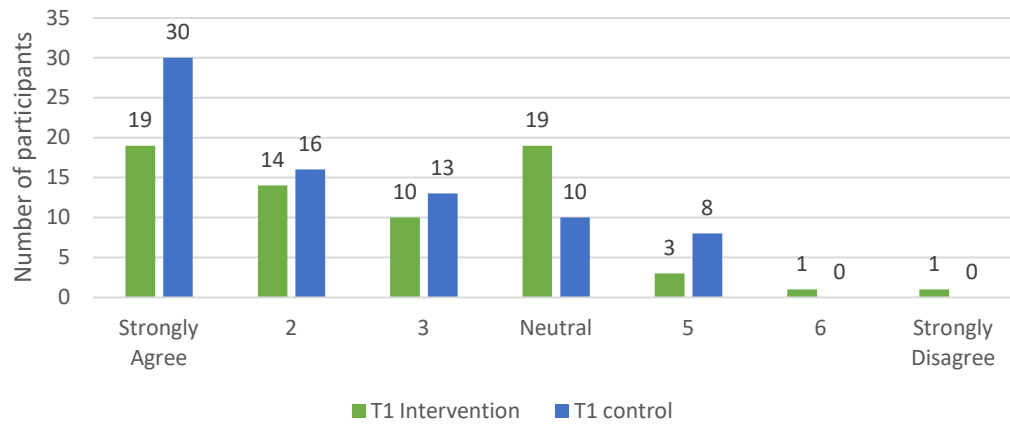
The longer I clean my teeth the less decay I will get



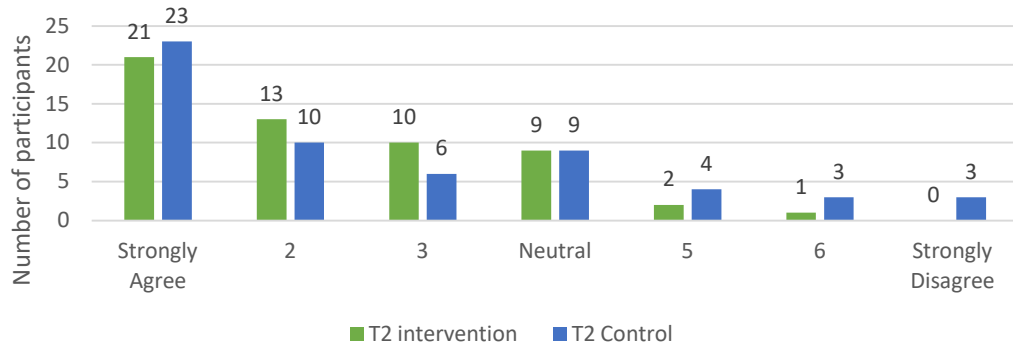
The longer I clean my teeth the less decay I will get



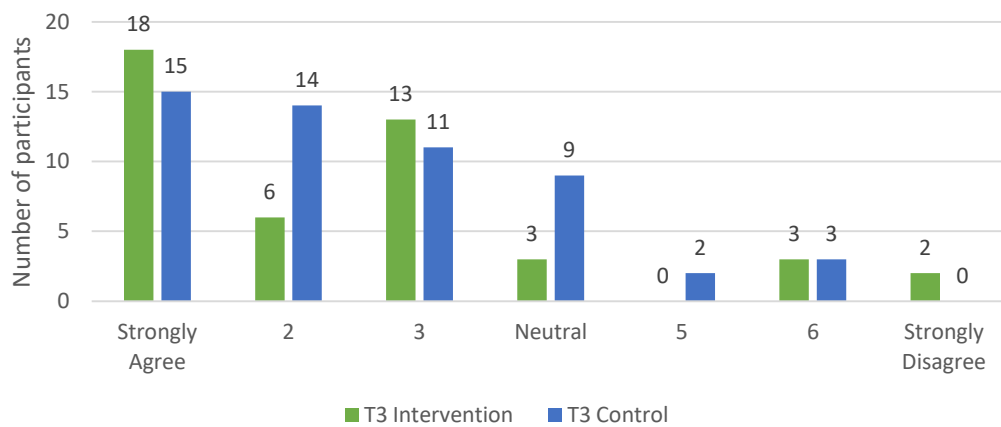
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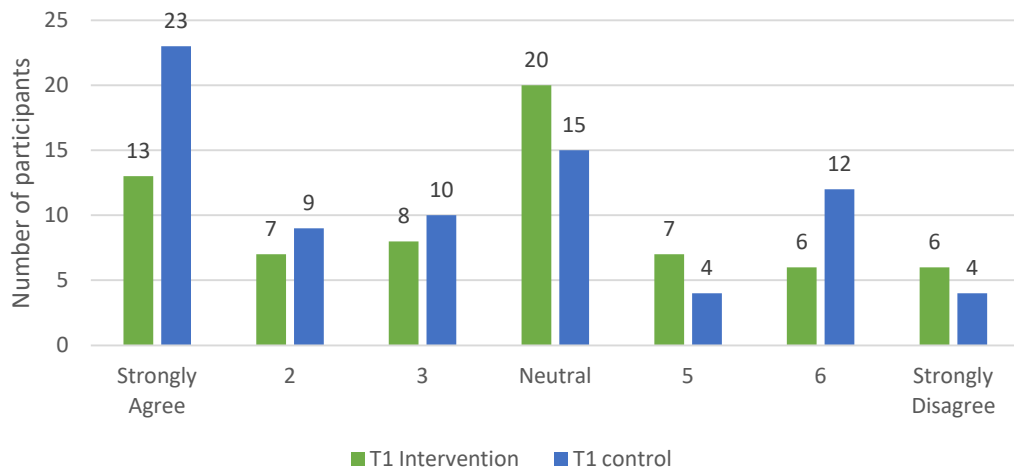
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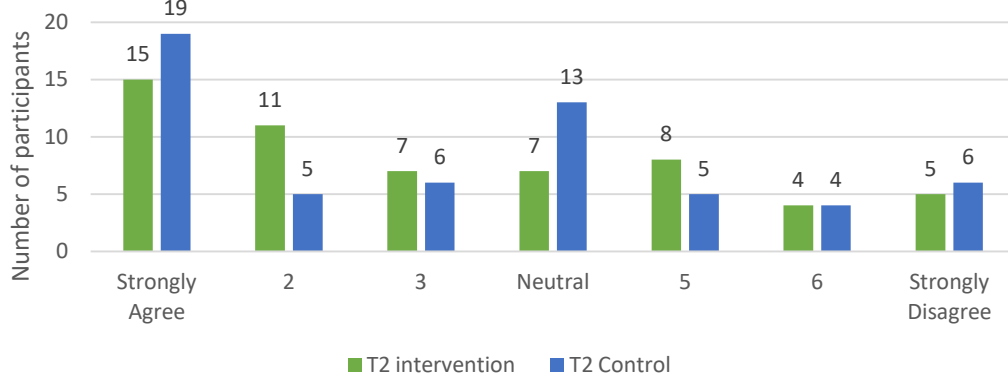
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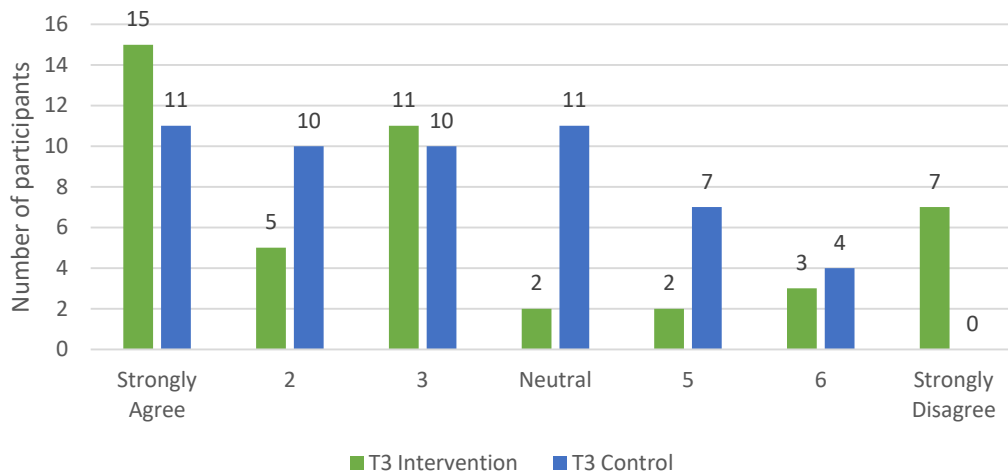
The longer I clean my teeth the less my gums will bleed



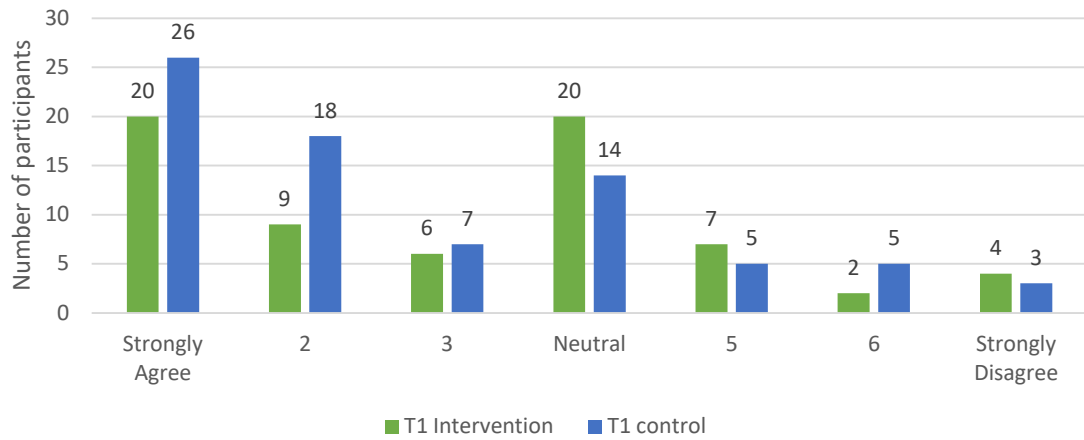
The longer I clean my teeth the less my gums will bleed



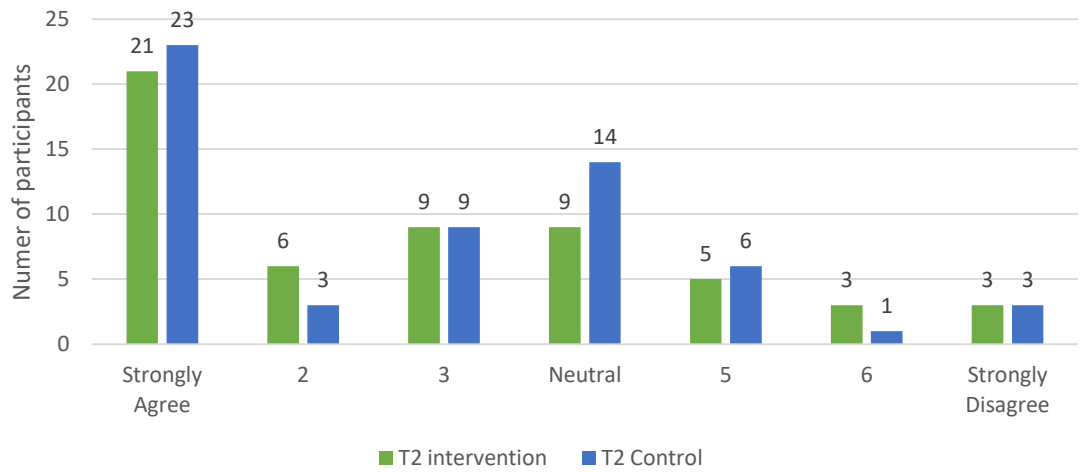
The longer I clean my teeth the less my gums will bleed



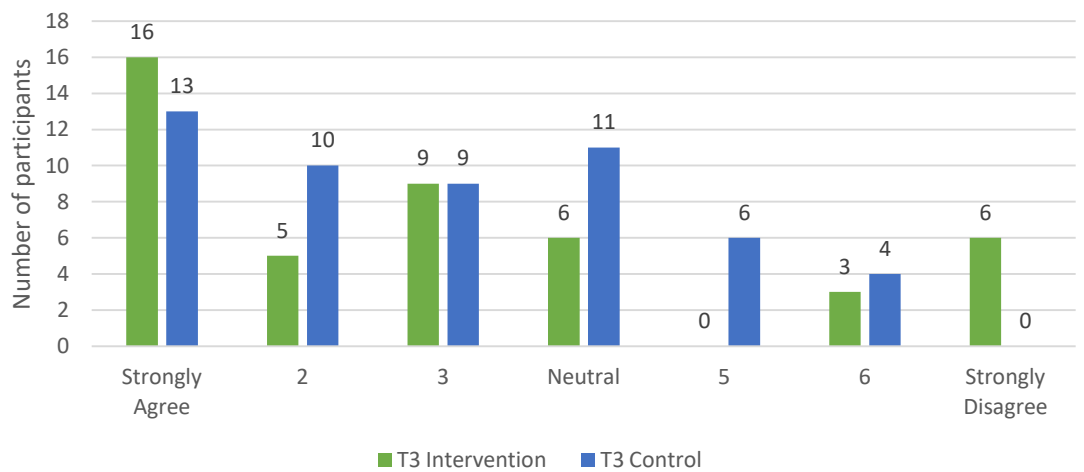
The more I clean my teeth the less my gums will bleed



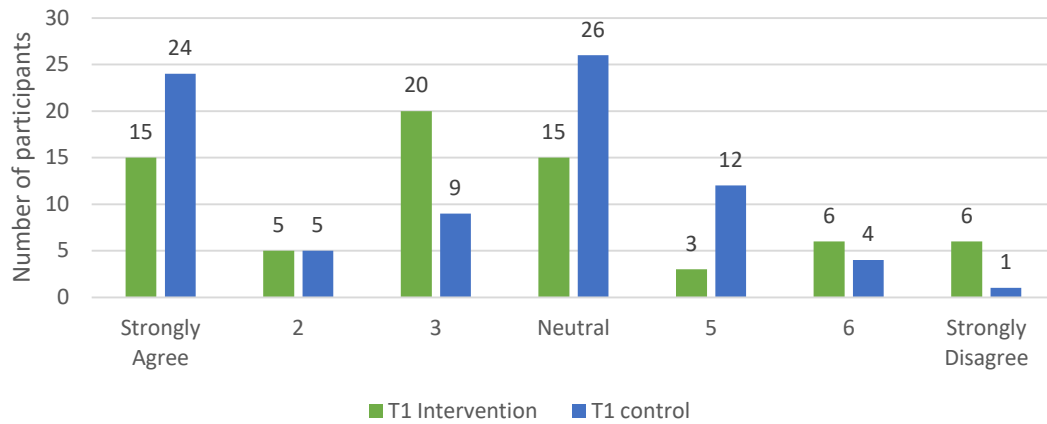
The more I clean my teeth the less my gums will bleed



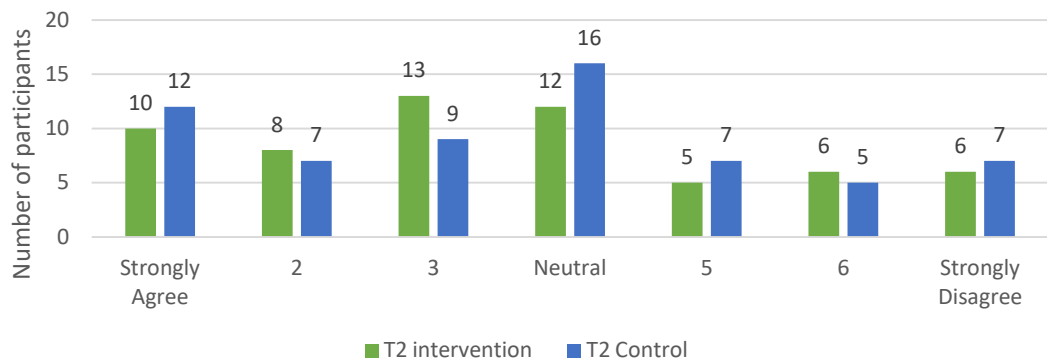
The more I clean my teeth the less my gums will bleed



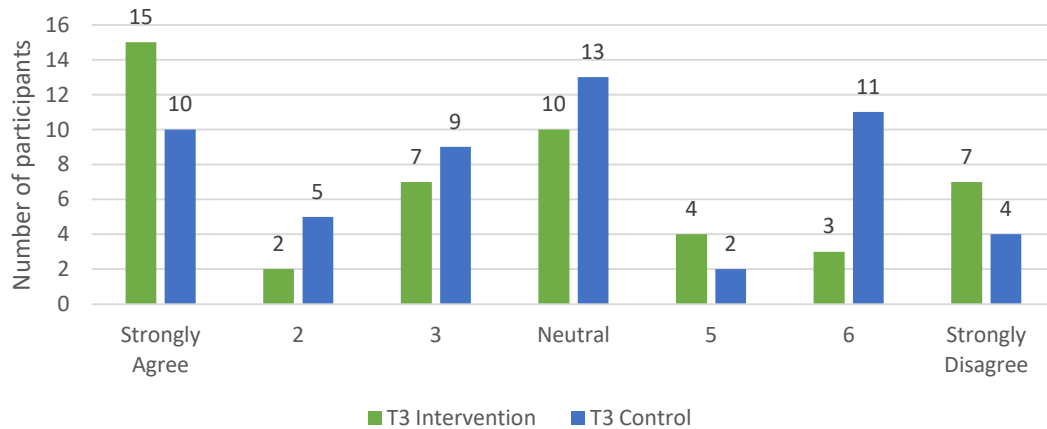
I think the dental students want me to clean my teeth differently from how I now clean them



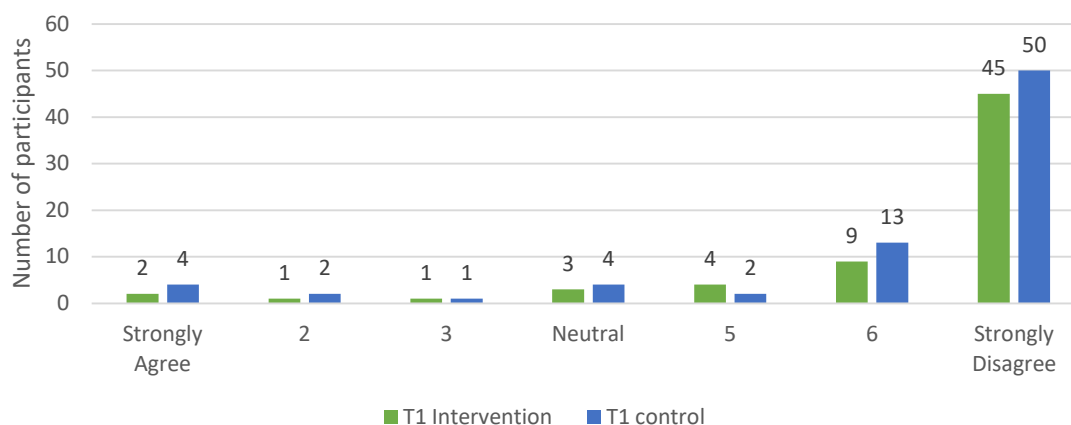
I think the dental students want me to clean my teeth differently from how I now clean them



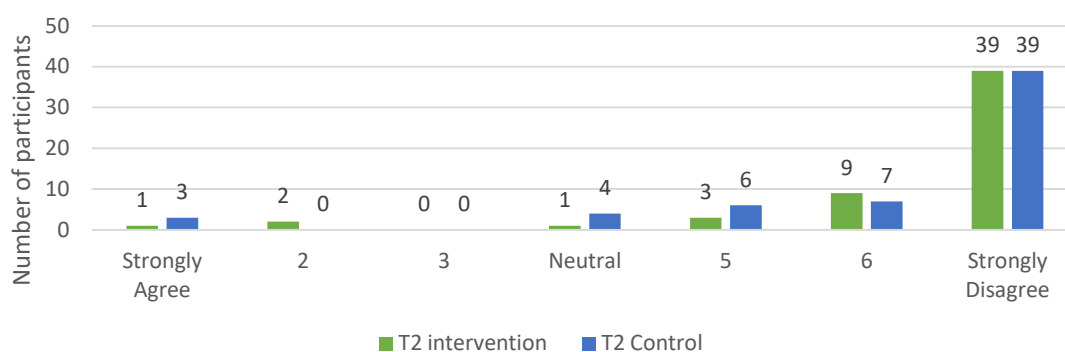
I think the dental students want me to clean my teeth differently from how I now clean them



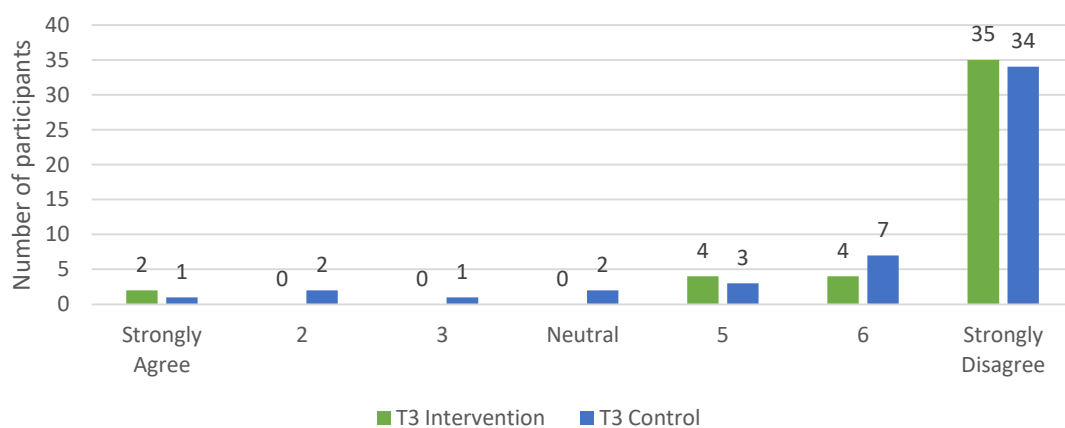
I don't care how the dental students think I should clean my teeth



I don't care how the dental students think I should clean my teeth



I don't care how the dental students think I should clean my teeth



Annual Outreach Monitoring Report (Extract for DOOHS Years)

Aggregate of Outreach Facilities Accommodating DDS Students

Placements	2013/14	2012/13	2011/12	2010/11	2009/10	2008/09	2007/08
Number of Days	1031	893	1058	901	880	798	458
Number of BDS Placements	5847	3717	4716	4467	5138	4114	2670
Number of DCP Placements	222	220	193	245	294	366	381

Patient Contacts	2013/14	2012/13	2011/12	2010/11	2009/10	2008/09	2007/08
Number of Adult Patient Contacts	12830	10781	13325	12491	11376	9276	6581
Number of Child Patient Contacts	134	106	99	128	179	342	295
Number of Senior Patient Contacts	3562	2025	2631	1828	1634	1145	912
Total number of Patient Contacts	16526	12912	16055	14447	13189	10763	7788
<i>Number of which were special needs</i>	619	281	50	48	71	94	62

Procedures	2013/14	2012/13	2011/12	2010/11	2009/10	2008/09	2007/08
Application of Desensitizing Agent	424	396	236	156	145	117	103
Behaviour (OHI, diet smoking, F, alcohol)	959	1074	2063	1353	1123	871	656
Bridge (fit)	84	87	462	390	339	324	213
Bridge (Prep)	82	78	577	633	674	528	399
Complete denture fit	365	307	433	384	690	600	511
Delivery of occlusal splint	61	50	22	n/r	n/r	n/r	n/r
Denture stage	n/r	n/r	3212	2759	2917	3067	2376
Diagnosis/Radiograph Rprt	3198	2403	n/r	n/r	n/r	n/r	n/r
Dressings	n/r	n/r	166	254	184	182	112
Examination/History	6987	5052	n/r	n/r	n/r	n/r	n/r
Extraction - deciduous tooth	23	22	42	44	27	44	29
Extraction - permanent tooth	2082	1518	2116	2053	1895	1629	1284
Extraction - surgical	17	14	23	22	23	40	27
Fissure Sealants	355	216	530	308	327	283	316
GA Assessments	2	1	8	19	13	20	8
Impressions	3423	3026	3245	2940	2430	1946	1436
Incision & drainage of abscess	22	19	11	13	n/r	n/r	n/r
Indirect restoration (fit)	283	251	181	54	63	n/r	n/r
Indirect restoration (prep)	298	287	66	71	49	n/r	n/r
Jaw relationship	648	399	n/r	n/r	n/r	n/r	n/r
Management of dental trauma	7	5	n/r	n/r	n/r	n/r	n/r
Management of soft tissue condition	72	77	n/r	n/r	n/r	n/r	n/r
Ortho Appliances Fitted/Adjusted	7	4	8	10	4	6	2
Other Procedures	311	316	642	757	610	811	661
Partial denture fit	511	448	494	425	n/r	n/r	n/r
Patient Assessments	n/r	n/r	9427	6437	5948	5899	1503
Periodontal pocket chart	213	192	298	292	185	121	116
Permanent restorations (amalgam)	1248	1085	1589	1470	1400	1491	1086
Permanent restorations (coloured)	3944	3639	5376	4770	4068	3530	2771
Plaque/Bleeding/Mobility Assessment	180	184	320	180	71	n/r	n/r
Post & core (fit)	49	50	n/r	n/r	n/r	n/r	n/r
Post & core (prep)	82	84	n/r	n/r	n/r	n/r	n/r
Prescriptions	179	177	163	95	52	100	48
Primary tooth - direct restorations	7	2	n/r	n/r	n/r	n/r	n/r
Primary tooth - pulp therapy	3	1	31	16	16	18	14
Provisional restorations	1407	1111	357	311	212	151	16
Radiographs	4231	3558	4525	4747	3873	3970	2574
RCT canal prep	670	566	n/r	n/r	n/r	n/r	n/r
RCT obturation	265	287	411	384	227	148	130
RCT other stage	247	317	793	777	752	534	457
Recement of indirect restoration	197	121	44	34	45	26	n/r
Referral/other correspondence	114	101	49	49	21	n/r	n/r
Relative analgesia/sedation	5	6	0	2	2	0	0
Removeable pros stage	2004	2047	n/r	n/r	n/r	n/r	n/r
Restoration adjustment	441	358	170	n/r	n/r	n/r	n/r
Root Surface Instrumentation	215	217	479	216	276	165	192
Scaling/Polishing	2362	1767	3143	2236	2265	1790	1216
Sensitivity tests	248	219	n/r	n/r	n/r	n/r	n/r
Stainless Steel Crowns	6	2	0	5	7	15	16
Stepwise Caries Treatment	47	71	26	26	35	n/r	n/r
Sutures - Placement/Removal	79	6	53	45	48	32	n/r
Temp Crown Made/Placed	n/r	n/r	54	88	n/r	n/r	n/r
Topical fluoride applications	236	194	176	149	130	142	90
Treatment of dry sockets	120	149	228	236	244	224	183
Treatment plan/consent	4156	2767	2045	1955	1379	1580	963
Treatment under GA	36	31	7	12	12	13	17
Treatment with LA	4464	4049	6393	5647	5206	4650	3492
Vitality Tests	n/r	n/r	9	20	21	7	n/r
Total	47676	39408	50703	42844	38008	35074	23017

n/r = Not recorded in this year

Appendix 20

Post Study Student Questionnaire



Dental Outreach Oral Hygiene Study

A Cluster Randomised Controlled Trial
investigating Oral Hygiene Advice and
Instruction in Dental outreach clinics in the east
of Scotland

Dental Student Post-Study Questionnaire



Instructions for Completing the Questionnaire

Thank you for collaborating during this trial. This trial aims to evaluate the effect of oral hygiene instruction delivered in the dental outreach clinics on outreach patients' oral hygiene and behaviour. Your beliefs and attitudes towards oral hygiene advice and clinical research in outreach are very important, and we would be grateful if you would complete this questionnaire after you have seen your last trial patient. The questionnaire is similar to the one you completed before beginning the trial. Although, some of the questions will appear to be very alike, **it is important for you to answer them all**. Try not to make a deliberate attempt to be consistent, just answer each question as honestly as possible, not what you believe you should answer or what we want to see. Finally, as before please be assured that your answers will be held in confidence and anonymised.

1. How confident are you that you can:	Not at All Confident				Extremely Confident		
a) Effectively give oral hygiene advice	1	2	3	4	5	6	7
b) Effectively advise about oral hygiene technique when giving oral hygiene advice?	1	2	3	4	5	6	7
c) Effectively demonstrate oral hygiene techniques?	1	2	3	4	5	6	7
d) Cope with taking part in a research project?	1	2	3	4	5	6	7
e) Fulfil the requirements of a research project?	1	2	3	4	5	6	7

2. In general, my giving advice about oral hygiene will:	Strongly Disagree				Strongly Agree		
a) Effectively reduce periodontal disease	1	2	3	4	5	6	7
b) Effectively increase plaque removal	1	2	3	4	5	6	7
c) Effectively reduce caries risk	1	2	3	4	5	6	7
d) Reduce the need for future treatment	1	2	3	4	5	6	7

3. In general, my demonstrating oral hygiene will:	Strongly Disagree				Strongly Agree		
a) Effectively reduce periodontal disease	1	2	3	4	5	6	7
b) Effectively increase plaque removal	1	2	3	4	5	6	7
c) Effectively reduce caries risk	1	2	3	4	5	6	7
d) Reduce the need for future treatment	1	2	3	4	5	6	7

4. In general:	Important				Unimportant		
a) My part in reducing periodontal disease is	1	2	3	4	5	6	7
b) My part in increasing plaque removal	1	2	3	4	5	6	7
c) My part in reducing caries risk is	1	2	3	4	5	6	7
d) My part in reducing the need for future treatment is	1	2	3	4	5	6	7

5. I find giving advice about oral hygiene is:								
a) Stressful	1	2	3	4	5	6	7	Pleasant
b) Embarrassing	1	2	3	4	5	6	7	Encouraging
c) Useful	1	2	3	4	5	6	7	Useless
d) Difficult	1	2	3	4	5	6	7	Easy

5. I find demonstrating oral hygiene is:								
a) Stressful	1	2	3	4	5	6	7	Pleasant
b) Embarrassing	1	2	3	4	5	6	7	Encouraging
c) Useful	1	2	3	4	5	6	7	Useless
d) Difficult	1	2	3	4	5	6	7	Easy

7. I think taking part in research is:								
a) Stressful	1	2	3	4	5	6	7	Pleasant
b) Embarrassing	1	2	3	4	5	6	7	Encouraging
c) Useful	1	2	3	4	5	6	7	Useless
d) Difficult	1	2	3	4	5	6	7	Easy

8. In regard to this research project:				Strongly Disagree			Strongly Agree		
a) I always give advice about oral hygiene when required	1	2	3	4	5	6	7		
b) I always demonstrated oral hygiene techniques when required	1	2	3	4	5	6	7		
c) I always coped with having to take part	1	2	3	4	5	6	7		
d) I always did exactly what I was required to do	1	2	3	4	5	6	7		

9.	a) What percentage of patients in the trial did you give advice about oral hygiene to?	%
	b) What percentage of patients in the trial did you give a demonstration of oral hygiene techniques to?	%
	c) What percentage of research project requirements did you not cope with?	%
	d) What percentage of research project requirements did you fulfil?	%
	e) How many patients did you recruit?	%

10. I find it difficult to give advice about oral hygiene if:				Strongly Disagree			Strongly Agree		
a)	The patient is a young child (less than 11)	1	2	3	4	5	6	7	
b)	The patient is an adolescent (11 to 16 years old)	1	2	3	4	5	6	7	
c)	The patient is an adult	1	2	3	4	5	6	7	
d)	The patient is a regular attender	1	2	3	4	5	6	7	
e)	The patient doesn't appear interested	1	2	3	4	5	6	7	
f)	The patient has untreated decay	1	2	3	4	5	6	7	
g)	The patient's oral hygiene is excellent	1	2	3	4	5	6	7	
f)	The surgery is running late	1	2	3	4	5	6	7	

11. I find it difficult to demonstrate oral hygiene techniques if:	Strongly Disagree				Strongly Agree		
a) The patient is a young child (less than 11)	1	2	3	4	5	6	7
b) The patient is an adolescent (11 to 16 years old)	1	2	3	4	5	6	7
c) The patient is an adult	1	2	3	4	5	6	7
d) The patient is a regular attender	1	2	3	4	5	6	7
e) The patient doesn't appear interested	1	2	3	4	5	6	7
f) The patient has untreated decay	1	2	3	4	5	6	7
g) The patient's oral hygiene is excellent	1	2	3	4	5	6	7
f) I am running late	1	2	3	4	5	6	7

12. I feel under pressure to give advice about oral hygiene:	Not at all				Very much		
a) From outreach patients	1	2	3	4	5	6	7
b) From the dental curriculum	1	2	3	4	5	6	7
c) From dental supervisors/consultants	1	2	3	4	5	6	7
d) From researchers	1	2	3	4	5	6	7

13. I feel under pressure to demonstrate oral hygiene techniques:	Not at all				Very much		
a) From outreach patients	1	2	3	4	5	6	7
b) From the dental curriculum	1	2	3	4	5	6	7
c) From dental supervisors/consultants	1	2	3	4	5	6	7
d) From researchers	1	2	3	4	5	6	7

14. I feel under pressure to take part in research:	Not at all				Very much		
a) From outreach patients	1	2	3	4	5	6	7
b) From the dental curriculum	1	2	3	4	5	6	7
c) From dental supervisors/consultants	1	2	3	4	5	6	7
d) From researchers	1	2	3	4	5	6	7

15. How motivated are you:	Not at all				Very much		
a) To do what patients think you should?	1	2	3	4	5	6	7
b) To do what the dental curriculum says you should?	1	2	3	4	5	6	7
c) To do what dental supervisors/consultants think you should?	1	2	3	4	5	6	7
d) To do what researchers think you should?	1	2	3	4	5	6	7

16. In future, it is likely that I will be able to:	Strongly Disagree				Strongly Agree		
a) Give advice about oral hygiene if required	1	2	3	4	5	6	7
b) Demonstrate oral hygiene if required	1	2	3	4	5	6	7
c) Cope with taking part in a research project	1	2	3	4	5	6	7
d) Fulfil the requirements of a research project	1	2	3	4	5	6	7

7. In general, participating in this trial has made me more confident about:	Strongly Disagree				Strongly Agree		
a) Participating in research	1	2	3	4	5	6	7
b) Recruiting patients for research	1	2	3	4	5	6	7
c) Fitting extra time required for research into my patient appointments	1	2	3	4	5	6	7
d) Fulfilling all the requirements of a research project	1	2	3	4	5	6	7
e) Starting research projects of my own	1	2	3	4	5	6	7

18. Before the trial began:	Yes	No	Not sure
a) Did you attend the lectures about clinical research and outreach?			
b) Did you read the information handouts?			
c) Did you access the information on My Dundee?			
d) Which of these was the most helpful and why?			

19. Overall, do you feel you were given:	Yes	No	Not sure
a) The correct amount of information?			
b) Too much information?			
c) Too little information?			
d) If you were not given the correct amount of information, please tell us how things could be improved?			

20. During the trial:	Strongly Disagree				Strongly Agree		
a) I could normally complete both clinical research and usual patient treatment at the same time	1	2	3	4	5	6	7
b) I often carried out radiographs or treatment planning and clinical research at the same appointment	1	2	3	4	5	6	7
c) I often carried out fillings or periodontal treatment, treatment planning and clinical research at the same appointment	1	2	3	4	5	6	7
d) I often carried out extractions or dental work and clinical research at the same appointment	1	2	3	4	5	6	7
e) I often carried out more complex treatment such as root treatment or crown work and clinical research at the same appointment	1	2	3	4	5	6	7

21. During the trial:	Strongly Disagree				Strongly Agree		
a) It was easy to follow the protocol	1	2	3	4	5	6	7
b) There was minimal disruption to the patient appointments	1	2	3	4	5	6	7

c) Patients were keen to take part	1	2	3	4	5	6	7
d) The clinics were well organised	1	2	3	4	5	6	7
e) I often required assistance from the dental nurse, regarding the trial protocol	1	2	3	4	5	6	7
f) I often required assistance from the outreach supervisor, regarding the trial protocol	1	2	3	4	5	6	7
g) I required assistance from the practice manager/receptionist, regarding the trial paperwork	1	2	3	4	5	6	7
h) I felt confident in what I was supposed to do	1	2	3	4	5	6	7

22. Which part of the trial did you find the easiest to cope with?	
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23. Which part of the trial did you find the most difficult to cope with?	
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24. Which part of the trial did you find the least time consuming?	
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25. Which part of the trial did you find the most time consuming?	
--	--

26. Did you find that it was easy to get any help you needed?

Yes ☐ No ☐ Not applicable ☐

27. If you contacted a member of the research support team were they helpful?

Yes ☐ No ☐ Not applicable ☐

28. In dental outreach research studies how important is it to you that:	Not at all Important				Very Important		
a) The research topic is relevant to outreach patients	1	2	3	4	5	6	7
b) The instructions are easy to follow	1	2	3	4	5	6	7
c) You can carry out normal patient treatments during research appointments	1	2	3	4	5	6	7
d) Your research team (your year) is named on the paper	1	2	3	4	5	6	7
e) Outreach patient are enthusiastic	1	2	3	4	5	6	7
f) Supervisors in outreach are enthusiastic	1	2	3	4	5	6	7

29. During the trial:	Strongly Disagree			Strongly Agree			
a) I referred to the trial information regularly	1	2	3	4	5	6	7
b) I asked advice from the research team	1	2	3	4	5	6	7
c) I asked advice from the outreach staff	1	2	3	4	5	6	7
d) I was confident carrying out the trial procedures without help	1	2	3	4	5	6	7
e) I was confident answering patient questions about the trial	1	2	3	4	5	6	7
f) I was confident in my knowledge of consent procedures	1	2	3	4	5	6	7
g) I was confident in filling in and returning the trial paperwork	1	2	3	4	5	6	7
h) I was confident in delivering oral hygiene instruction/advice	1	2	3	4	5	6	7
i) I felt out of my depth more than usual	1	2	3	4	5	6	7
j) I accessed materials on My Dundee (video/information etc)	1	2	3	4	5	6	7
k) I often ran late	1	2	3	4	5	6	7
l) I often could carry out other dental treatment for patients, as well as the research within the appointment time	1	2	3	4	5	6	7
m) The outreach patients were enthusiastic	1	2	3	4	5	6	7
n) I had difficulty recruiting enough patients	1	2	3	4	5	6	7
o) The outreach staff were enthusiastic	1	2	3	4	5	6	7
p) I effectively managed the time required for the trial during the appointment times	1	2	3	4	5	6	7
q) I recruited as many patients as I wanted to	1	2	3	4	5	6	7

30. Participating in clinical research during outreach:	Strongly Agree			Strongly Disagree			
a) Was enjoyable for me	1	2	3	4	5	6	7
b) Improved my future employment opportunities	1	2	3	4	5	6	7
c) Taught me new skills	1	2	3	4	5	6	7
d) Was confusing	1	2	3	4	5	6	7
e) Was stressful	1	2	3	4	5	6	7
f) Improved my understanding of research	1	2	3	4	5	6	7
g) Was of benefit to me							

31. Participating in clinical research during outreach:	Strongly Agree			Strongly Disagree			
a) I believe dental undergraduates should have the opportunity to participate in clinical research during outreach	1	2	3	4	5	6	7
b) I believe dental undergraduates can achieve the skills required to carry out clinical research during outreach placements	1	2	3	4	5	6	7
c) I intend to take part in clinical research in the future	1	2	3	4	5	6	7
d) I believe taking part in clinical research should be part of the undergraduate curriculum	1	2	3	4	5	6	7
e) I believe dental outreach clinics are a good research environment	1	2	3	4	5	6	7

If you would like to expand on any of your answers or would like to comment about any part of the study, please use the box below:

Thank you for taking the time to complete this questionnaire.
Your help during this trial is appreciated.

Appendix 21

Post Study Staff Questionnaire



Dental Outreach Oral Hygiene Study

Outreach Supervisor Post-Study
Feedback Questionnaire



TAHSC
Tayside Academic Health Sciences Centre



Instructions for Completing the Questionnaire

Thank you supervising this clinical trial. This trial aims to evaluate the effect of oral hygiene instruction delivered in the dental outreach clinics on outreach patients' oral hygiene and behaviour. Your observations of the trial and the impact on your outreach clinic, is very important, and we would be grateful if you would complete this questionnaire. Finally, please be assured that your answers will be held in confidence and anonymised.

1. Before the trial began:	Yes	No	Not sure
a) Did you attend the lectures about clinical research and outreach trial?			
b) Did you use the information handouts?			
c) Did you access the information on My Dundee?			
d) Which of these was the most helpful and why?			

2. Overall, did you feel as a supervisor you received:	The correct amount of information	Too much information	Too little information
d) If you were not given the correct amount of information, please tell us how things could be improved?			

3. Did you find that it was easy to contact a member of the research support team?

Yes ☐ No ☐ Not applicable ☐

4. If you contacted a member of the research support team were they helpful?

Yes ☐ No ☐ Not applicable ☐

5. In future student outreach research projects:	Strongly Agree				Strongly Disagree		
a) I think students should be given the opportunity to help decide the research topic	1	2	3	4	5	6	7
b) I think students should be given the opportunity to help decide the study protocol	1	2	3	4	5	6	7
c) I think supervisors should be given the opportunity to help decide the research topic	1	2	3	4	5	6	7
d) I think supervisors should be given the opportunity to help decide the study protocol	1	2	3	4	5	6	7
e) I would be willing to participate in deciding the research topic	1	2	3	4	5	6	7
f) I would be willing to participate in the development of the study protocol	1	2	3	4	5	6	7
g) I think students should have the opportunity to take part in a research study	1	2	3	4	5	6	7
h) I think supervisors should have the opportunity to take part in research study	1	2	3	4	5	6	7

6. Do you believe clinical studies **can** be carried out successfully in dental outreach?

Yes ☐

No ☐

Not sure ☐

7. Do you believe clinical studies **should** be carried out in dental outreach?

Yes ☐

No ☐

Not sure ☐

8. In future dental outreach research studies how important is it that:	Not at All Important				Very Important		
a) The research topic is relevant to the outreach patients	1	2	3	4	5	6	7
b) The study protocol is easy to administer	1	2	3	4	5	6	7
c) Any disruption to dental outreach is minimised	1	2	3	4	5	6	7
d) Research studies are CPD accredited	1	2	3	4	5	6	7

9. During the trial:	Strongly Agree				Strongly Disagree		
a) The students managed to carry out both clinical research and patient treatment at the same appointment	1	2	3	4	5	6	7
b) The students often carried out radiographs or treatment planning and clinical research at the same appointment	1	2	3	4	5	6	7
c) The students often carried out fillings or periodontal treatment and clinical research at the same appointment	1	2	3	4	5	6	7
d) The students often carried out extractions or dental work and clinical research at the same appointment	1	2	3	4	5	6	7
e) The students often carried out more complex treatment such as root treatment or crown work and clinical research at the same appointment	1	2	3	4	5	6	7
a) I could normally complete both clinical research and usual patient treatment at the same time	1	2	3	4	5	6	7
b) I often carried out radiographs or treatment planning and clinical research at the same appointment	1	2	3	4	5	6	7
c) I often carried out fillings or periodontal treatment planning and clinical research at the same appointment	1	2	3	4	5	6	7

10. During the trial:	Strongly Agree				Strongly Disagree		
a) It was easy to follow the protocol	1	2	3	4	5	6	7
b) There was minimal disruption to the patient appointments	1	2	3	4	5	6	7
c) Patients were keen to take part	1	2	3	4	5	6	7
d) The clinics were more stressful to supervise than usual	1	2	3	4	5	6	7
e) I required support from the dental nurse, in managing the student activities more than usual	1	2	3	4	5	6	7
f) The student needed much more support than usual	1	2	3	4	5	6	7
g) The clinic was more challenging to supervise	1	2	3	4	5	6	7
h) I felt confident in what the students were supposed to do	1	2	3	4	5	6	7
i) The students were enthusiastic	1	2	3	4	5	6	7
11. Participating in clinical research while supervising outreach	Strongly Agree				Strongly Disagree		
a) Was enjoyable for me	1	2	3	4	5	6	7